

COMMITTEE ON SAFETY OF MEDICINES

Edited and Selected Extracts
from the
REGISTER OF ADVERSE REACTIONS

Covering the period January 1964 to October 1971

VOLUME II (pages 323 to 626)



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Corticotrophin Zinc (50003)

Cortrophin-ZN

Total reports December 1966-October 1971 7 (1 fatal)

Reports not listed NIL

| | Total | Deaths |
|------------------------|-------|--------|
| Diabetes mellitus | 1 | |
| Oedema | 1 | |
| Vertigo | 1 | |
| Peptic ulcer | 1 | 1 |
| Skin reactions | 2 | |
| Inflamation following | | |
| subcutaneous injection | 1 | |

| Prescriptions | (EC | 10) | for | 1968 | 7,000 |
|---------------|-----|-----|------|------|-------|
| i ii | 1 | 1 | 11 | 1969 | 7.000 |
| j1 | | 1 | . 11 | 1970 | 3,000 |

Corticotrophin C.M.C. (50004)

Total reports February 1967-October 1971 3
Reports not listed 1

Total Deaths

Skin reactions 2

 "
 "
 1969
 16,000

 "
 "
 1970
 17,000

Tetracosactrin (50051)

'Cortrosyn', 'Synacthen'

Total reports December 1968-October 1971 71 (5 fatal) Reports not listed 9

| | Total | Deaths |
|-------------------------------|-------|--------|
| Diabetes mellitus | 1 | |
| Oedema | 7 | |
| Fluid retention | 1 | |
| Syncope | | |
| Somnolence | | |
| Flushing | | |
| Tremor | | |
| Sensory disturbance | 1 | |
| Conjunctivitis | 1 | |
| Vertigo | 1 | |
| Hypotension | 2 | |
| Hypertension | 1 | |
| Cardiac arrest | 2 | 2 |
| Heart failure | 1 | 1 |
| Bronchospasm | 6 | |
| Dyspnoea | 1 | |
| Intestinal perforation | | 1 |
| Gastro-intestinal haemorrhage | 2 | |
| Glycosuria | 1 | |
| Urticaria | 5 | |
| Angioneurotic oedema | 1 | |
| Purpura | 1 | |
| Pigment change | 1 | |
| Other skin reactions | 3 | |
| Anaphylactic shock | 7 | 1 |
| Anaphylaxis | 5 | |
| Rigor | . 1 | |
| Inflammation following | | |
| intra-muscular injection | 2 | |
| Oedema following | | |
| intra-muscular injection | 1 | |

Oxytocin (50101)

'Pitocin'

Total reports March 1964-October 1971 16 (1 fatal)

Reports not listed Nil

| | Total | Deaths |
|--------------------------|-------|--------|
| Convulsion | 1 | |
| Subarachnoid haemorrhage | 2 | 1 |
| Hypertension | 3 | |
| Amniotic embolism | 1 | |
| Arrhythmia | 1 | |
| Bronchospasm | 1 | |
| Stomatitis | 1 | |
| Rupture of uterus | 5 | |
| Skin reactions | 1 | |

Syntocinon (Synthetic Oxytocin) (50102)

'Syntocinon', 'Syntometrine'

Total reports Deptember 1964-October 1971 6 (1 fatal)

Reports not listed 3

| | Tota1 | Deaths |
|---------------|-------|--------|
| Coma | 1 | |
| Renal failure | 2 | 1 |

Lypressin (50112)

'Syntopressin'

Total reports October 1966-October 1971 1

Reports not listed Nil

Felypressin (50121)

'Octapressin'

Total reports February 1969-October 1971 6 Reports not listed 2

| | Total | Deaths |
|-----------------|-------|--------|
| Mental disorder | 2 | 7 |
| Neuritis | 2 | |

Chorionic Gonadotrophin (50201)

Gestyl, *Gonadotraphon*, *Pregnyl*

Total reports May 1969-October 1971 2

Reports not listed Nil

| | | Tota1 | Deaths |
|--------|--------------------|-------|--------|
| | mia | | |
| Inflam | mation following | | |
| Intra- | muscular injection | . 1 | |

Ethinyloestradiol (51010) with Norethisterone (52103)

'Anovlar'

Total reports March 1964-December 1971 318 (19 fatal)

| | | | | Total | Deaths |
|--|-------|-------|--------------------------|-------|--------|
| | Total | Death | S | | |
| | | | Thrombophlebitis | 14 | |
| Goitre | 1 | | Pulmonary embolism | 19 | 1 |
| Amenorrhea | 4 | | Thrombosis, peripheral | | |
| Breast hypertrophy | | | artery | 1 | |
| (female) | 1 | | Budd-Chiari Syndrome | 2 | |
| Dysmenorrhoea | 1 | | Vasoconstriction | 2 | |
| Diabetes mellitus | 1 | | Haemorrhoids | 1 | |
| Weightgain | 10 | | | 2 | |
| Weightloss | 1 | | Painful veins | - 1 | |
| Gout | 1 | | Tachycardia | 2 | |
| Coproporphyrinurea | 1 | | Angina | 16 | 8 |
| Oedema | 1 | | Coronary occlusion | | |
| Thrombocytopenia | 2 | | Chestpain | 1 1 | |
| Pancytopenia | 1 | 1 | Dyspnoea | 15 | |
| Depression | 4 | | Jaundice | • | |
| Mental symptoms | | | Hepatomegaly, | 1 | |
| following withdrawal | 1 | | not jaundical | • 7 | |
| Emotional change | 1 | | Diarrhoea | • 1 | |
| Debility | 2 | | Nausea and vomiting | • 3 | |
| Reduced libido | 6 | | Abdominal pain | • 1 | |
| Neuritis | 1 | | Nephropathy | • 1 | |
| Paralysis | 1 | | Cervicitis | 1 | |
| Convulsion | 2 | | Urticaria | • 1 | |
| Cerebrovascular disorders | 10 | | Morbilliform rash | • 2 | |
| | 6 | 3 | Erythema nodosum | • 6 | |
| Subarachnoid haemorrhage Cerebral thrombosis | 13 | 4 | Alopecia | • 1 | |
| | 11 | _ | Hypertrichosis | . 1 | |
| Headache | 9 | | Hair colour change | • | |
| Nigraine | 2 | | Pigment change | . 9 | |
| Sweating | 2 | | Hyperpigmentation | • 1 | |
| Paraesthesia | . 2 | | Vitiligo | • | |
| Ciddiness | 1 | | Pruritus | . 1 | |
| Papilloedema | 34. | | Acne | . 1 | |
| Retinal artery | 1 | | Other skin reactions | | |
| thrombosis | 2 | | Congenital abnormalities | . 2 | |
| Visual disturbance | | | Intrauterine death | . 1 | |
| Hypertension | 11 | 1 | Pregnancy while on | | |
| Superficial venous | 27 | | oral-contraceptives | 7 | |
| thrombosis | 0.03 | | Arthralgia | 4 | |
| Deep venous thrombosis | ^ | | Muscle pain |] | |
| Thrombosis portal vein | . · 2 | 1 | Sepsis | | |
| Venous thrombosis, site | | | Carcinoma of breast | | |
| not stated | . 1 | | | | |

Ethinyloestradiol (51010) with Norethisterone (52103)

'Gynovlar'

Total reports March 1964-December 1971 1,078 (40 fatal)

| To | otal | Deaths | t . | Total | Deaths |
|--------------------------|---------|--------|--------------------------|-------|--------|
| Goitre | 1 | | Deep venous thrombosis | 96 | |
| Hyperthyroidism | _ | | Thrombosis portal vein | 2 | 2 |
| Thyroid neoplasm | | | Venous thrombosis, site | | |
| Menorrhagia | | | not stated | 2 | |
| Menstrual irregularities | | | Thrombophlebitis | 39 | |
| Amenorrhoea | | | Pulmonary embolism | 78 | 12 |
| Lactation | | | Thrombosis, peripheral | | |
| Breast hypertrophy | | | artery | 3 | |
| (female) | 14 | | Budd-Chiari Syndrome | 1 | |
| Break-through bleeding | | | Vasoconstriction | 4 | |
| Diabetes mellitus | | | Painful veins | 12 | |
| Hyperglycaemia | | | Palpitations | 1 | |
| Weightgain | | | Tachycardia | 1. | |
| Oedema | - | | Angina | 5 | |
| Fluid retention | | | Coronary occlusion | 35 | 14 |
| Thrombocytopenia | | | Heart failure | 1 | |
| Macrocytic anaemia | | | Chestpain | 12 | |
| Psychosis | | • | Dyspnoea | 5 | |
| Depression | | 1 | Cough | 1 | |
| Mental symptoms | ! | | Rhinitis | 1 | |
| following withdrawal | .: 8 | | Epistaxis | 1 | |
| Emotional change | | | Heamoptysis | 1 | |
| Mental disorder | | | Jaundice | 15 | 1 |
| Debility | _ | | Hepatomegaly, not | _ | |
| Reduced libido | | | jaundical | 1 | |
| Encephalitis | | | Abnormal liver function | _ | |
| Neuritis | | ! | tests | 5 | |
| Paralysis | _ | | Colitis | 2 | |
| Extrapyramidal symptoms | , 1 | _ | Dental caries | 1 | |
| Convulsion | . 1 | 3 | Stomatitis | 1 | |
| Syncope | . 4 | 1 | Diarrhoea | 4 | |
| Somnolence | | L | Nausea and vomiting | 12 | |
| Cerebrovascular | | | Abdominal pain | 7 2 | |
| disorders | . •, 21 | 0 | Renal calculus | 6 | |
| Subarachnoid | | | Vaginitis | . 2 | |
| haemorrhage | | 3 | Urticaria | 4 | |
| Cerebral thrombosis | / | | Purpura | 1 | |
| Headache | | | Erythema multiforme | 8 | |
| Photophobia | | 1 | Erythema nodosum | 5 | |
| Migraine | 1 | | Photosensitivity | í | |
| Sweating | | 2 | Eczema | 18 | |
| Flushing | • • | 1 | Alopecia | 2 | |
| Generalised weakness | | 1 | Hair colour change | 12 | |
| Anaesthesia | • • ; | 1 | Pigment change | 1 | |
| Paraesthesia | | 7 | Moniliasis | 2 | |
| Giddiness | | 1 | Proriasis | 2 | |
| Conjunctivitis | • • | 4 | Pruritus | 4 | |
| Corneal ulceration | • • | | Other skin reactions | 22 | |
| Cataract | | 1 | Congenital abnormalities | 2 | |
| Papilloedema | | 1 | Pregnancy while on | | |
| Retinal artery | • • • | _ | oral-contraceptives | 30 | |
| thrombosis | | 4 | Arthralgia | 8 | |
| Visual disturbance | ••• | 5 | Muscle pain | 12 | |
| Ptosis | | 1 | Sepsis | 2 | |
| Blindness | | | Fibroid | 1 | |
| Hypertension | | 2 | Carcinoma of breast | 7 | 1 |
| Superficial venous | | | Carcinoma of cervix | 3 | |
| thrombosis | ••• 6 | 6 | Thrombosis following | | |
| | | | intra-venous injection | 1 | |

Ethinyloestradiol (51010) with Norethisterone (52103)

'Minovlar'

Total reports August 1968-December 1971 389 (21 fatal)

| | Total | Deaths | | Total | Deaths |
|--------------------------------|-------|--------|-------------------------|------------|--------|
| Hyperthyroidism | 1 | | Venous thrombosis (site | | |
| Thyroid function studies | | | not stated | 2 | |
| Amenorrhoea | | | Thrombophlebitis | 6 | |
| Lactation | | | Intracraniel venous | | |
| Breast hypertrophy | | | thrombosis | 4 | |
| (female) | 2 | | Pulmonary emolism | 5 8 | 12 |
| Dysmenorrhoea | 1 | | Thrombosis peripheral | | |
| Break-through bleeding | | | artery: | 3 | |
| Weightgain | | | Vasoconstriction | 1 | |
| Porphyria | | | Vasculitis | 2 | |
| Oedema | | | Painful veins | 3 | |
| Depression | | | Cardiac arrest | 1 | 1 |
| Mental disorder | | | Angina | 2 | |
| Debility | | | Coronary occlusion | 11 | 6 |
| Reduced libido | | | Chest pain | 2 | |
| Convulsion | | | Bronchospasm | , 2 | |
| Petit-mal convulsion | | | Dyspnoea | _ | |
| Syncope | | | Haemoptysis | | |
| Cerebrovascular disorders | _ | | Jaundice | | |
| | | | Cholecystitis | | |
| Subarachnoid haemorrhage | | 1 | m Maria | 1 | |
| Cerebral thrombosis | | _ | Gingivitis | 1 | |
| Headache | | | Stomatitis | | |
| Migraine | | | Diarrhoea | | |
| Paraesthesia | | | Vaginitis | _ | |
| Sweating | Ī | | Urticaria | _ | |
| Sensory disturbance | | | Purpura | | |
| Abnormal movements | | | Erythema nodosum | | |
| Giddiness | | | Photosensitivity | | |
| Optic neuritis | . 2 | | Alopecia | | |
| Difficulty in using | | | Hypertrichosis | | |
| contact lens | | | Pigment change | _ | |
| Retinal vein thrombosis | | | Psoriasis | _ | |
| Retinal artery thrombosis | _ | | Acne | | |
| Blindness | | | Other skin reactions | 1 | |
| Vertigo | | | Pregnancy while on | , ••• | |
| Taste abnormality | | | oral-contraceptives | ., 39 | |
| Hypotension | | | | | |
| Hypertension | | | Joint symptoms | | |
| Superficial venous thrombosis. | 1 | | Muscle pain | | |
| Deep venous thrombosis | 60 |) | Carcinoma of breast | | |
| Thrombosis superior | | | | | |
| vena cava | ••• 1 | | .Carcinoma of cergix | , , | |

Ethinyloestradiol (51010) with Norethisterone (52103)

'Minovlar ED'

Total reports August 1970-December 1971 5

| | Total | Deaths |
|------------------------|-------|--------|
| Hypertension | 1. | |
| Deep venous thrombosis | 1 | |
| Pulmonary embolism | 2 | |
| Pregnancy while on | | |
| oral-contraceptives | 1 | |

ORAL-CONTRACEPTIVE AGENTS Sphinylpestradio1 (51010) with Norethisterone (52103)

'Norlestrin'

Total reports March 1964-December 1971 118 (6 fatal)

| | Total | Deaths | | Total | Deaths |
|-----------------------------|-------|--------|---------------------------------|-------|--------|
| Steriod-withdrawal syndrome | 2 | | Superficial venous thrombosis . | 12 | |
| Amenorrhoea | 1 | | Deep venous thrombosis | | |
| Lactation | . 1 | | Thrombophlebitis | | |
| Breast hypertrophy (female) | | | Pulmonary embolism | | 2 |
| Break-through bleeding | 1 | | Gangrene | | |
| Loss of control of diabetes | | | Painful veins | | |
| Weightgain | 1 | | Coronary occlusion | | 2 |
| Oedema | | | Dyspnoea | | 2 |
| Haemolytic anaemia | 1 | | Epistaxis | | |
| Depression | | | Jaundice | | |
| Mental symptoms following | | | Proctitis | | |
| withdrawal | 2 | | Glossitis | | |
| Reduced libido | | | | | |
| Neuropathy | | | Oesophagitis | | |
| Syncope | 1 | | · · | | |
| Cerebrovascular disorders | | 1 | Abdominal pain | | |
| Cerebral thrombosis | 1 | _ | Vaginitis | _ | |
| Headache | | | Purpura | | |
| Migraine | | 1 | Alopecia | | |
| Gait disorder | | _ | Hypertrichosis | | |
| Stammer | | | Pigment change | | |
| Visual disturbance | | | Acne | | |
| | | | Other skin reactions | . 2 | |
| Diplopia | 1 | | Pregnancy while on | | |
| Blindness | | | oral-contraceptives | . 1 | |
| Hypertension | 7 | | | | |

Ethinyloestradiol (51010) with Norethisterone (52103)

'Orlest 28'

Total reports March 1964-December 1971 10

| | Total | Deaths |
|-------------------------------|-------|--------|
| Cerebrovascular disorders | 2 | |
| Hypertension | 1 | |
| Superficial venous thrombosis | 1 | |
| Pulmonary embolism | 3 | |
| Skin reaction | 1 | |
| Pregnancy while on | | |
| oral-contraceptives | 2 | |

Ethinyloestradiol (51010) with Norethisterone (52103)

1Primodos1

Total reports March 1964-December 1971 13

| | Total | Deaths |
|-------------------------------|-------|--------|
| Hyperthyroidism | 1 | |
| Superficial venous thrombosis | 2 | |
| Uraemia | 1 | |
| Abortion | 4 | |
| Congenital abnormalities | 5 | |

Ethinyloestradiol (51010) with Megestrol (52117)

'Serial 28'

Total reports March 1964-December 1971 55 (2 fatal)

| | Total | Deaths |
|------------------------------|-------|--------|
| Menorrhagia | 2 | |
| Oedema | | |
| Depression | 1 | |
| Convulsion | 1 | |
| Headache | 1 | |
| Paraesthesia | | |
| Abnormal movements | | |
| Deep venous thrombosis | | |
| Venous thrombosis, site | | |
| not stated | 1 | |
| Thrombophlebitis | | |
| Pulmonary embolism | | 2 |
| Thrombosis peripheral artery | 1 | |
| Vasculitis | 1 | |
| Jaundice | 1 | |
| Skin reactions | | |
| Congenital abnormality | 1 | |
| Pregnancy while on | | |
| oral-contraceptives | 26 | |
| Carcinoma of breast | 1 | |

Ethinyloestradiol (51010) with Ethynodiol (52112)

'Ovulen 50'

Total reports March 1970-December 1971 81 (3 fatal)

| | Total | Deaths |
|--------------------------------------|-------|--------|
| Amenorrhoea | 1 | |
| Breast hypertrophy (female) | 1 | |
| Break-through bleeding | 1 | |
| Weightgain | 1 | |
| Macrocytic anaemia | | |
| Depression | | |
| Mental symptoms following withdrawal | | |
| Mental disorder | 1 | |
| Debility | 1 | |
| Cerebrovascular disorders | 2 | |
| Cerebral thrombosis | 6 | |
| Headache | 4 | |
| Visual disturbance | 1 | |
| Hypertension | | |
| Superficial venous thrombosis | 4 | |
| Deep venous thrombosis | 18 | |
| Pulmonary embolism | 15 | 3 |
| Thrombosis, peripheral artery | 1 | |
| Coronary occlusion | 2 | |
| Nausea and vomiting | 1 | |
| Vaginitis | 1 | |
| Cervical (uterine) polyps | 1 | |
| Abortion | 1 | |
| Skin reactions | 4 | |
| Pregnancy while on | | |
| oral-contraceptives | 6 | |
| Carcinoma of cervix | 1 | |

Ethinyloestradiol (51010) with Lynoestrenol (52110)

'Minilyn'

Total reports February 1970-December 1971 134 (6 fatal)

| | Total | Deaths | | Total | Deaths |
|--|--|--------|---|-------------------------|-------------|
| Hyperthyroidism Breast Hypertrophy (female) Weightgain Oedema Depression Mental disorder Reduced libido Petit mal convulsion Syncope Somnolence Cerebral thrombosis Headache Migraine Paraesthesia Sensory disturbance | 1 6 1 4 3 3 1 1 7 4 2 7 | Deaths | Thrombosis (peripheral artery) Coronary occlusion Heart failure Dyspnoea Jaundice Ileitis Stomatitis Urticaria Erythema nodosum Pigment change Vitiligo Pruritus Acne Other skin reactions Pregnancy while on oral-contraceptives | . 1 3 1 1 2 1 5 3 1 2 4 | Deaths 1 1 |
| Sleep disorder | 1 1 2 | | Shivering | 1 | |
| Superficial venous thrombosis Deep venous thrombosis Thrombophlebitis Intracranial venous thrombosis Pulmonary embolism | 10 16 2 | 1 3 | Carcinoma of breast | 1 | |

Ethinyloestradiol (51010) with Ethynodiol (52112)

Demulen 50

Total reports August 1970-December 1971 6

| | Total | Deaths |
|----------------------|-------|--------|
| Amenorrhoea | 1 | |
| Petit mal convulsion | 1 | |
| Migraine | 1 | |
| Skin reaction | 1 | |
| Pregnancy while on | | |
| oral-contraceptive | 2 | |

Ethinyloestradiol (51010) with Megestrol (52117)

'Volidan'

Total reports March 1964-December 1971 307 (11 fatal)

| | Total | Deaths | | Total | Deaths |
|--------------------------|-------|--------|-------------------------|-------|--------|
| Thyroid function studies | 1 | | Pulmonary embolism | 43 | 7 |
| Menorrhagia | 1 | | Thrombosis, peripheral | | |
| Menstrual irregularities | 3 | | artery | 1 | |
| Amenorrhoea | 2 | | Budd-Chiari Syndrome | 1 | |
| Breast hypertrophy | | | Vasoconstriction | 2 | |
| (female) | 1 | | Vascular disorders | 1 | |
| Break-through bleeding | 5 | | Painful veins | 1 | |
| | 7 | | Tachycardia | 2 | |
| Weightgain | 1 | | Angina | 4 | |
| Porphyria | 3 | | Coronary occlusion | 3 | 2 |
| Oedema | í | | Chestpain | 2 | |
| Fluid retention | 1 | | Bronchospasm | 1 | |
| Psychosis | 7 | | Dyspnoea | 1 | |
| Depression | • | | Rhinitis | 1 | |
| Mental symptoms | 1 | | Epistaxis | ı | |
| following withdrawal | 12 | | Jaundice | 5 | 1 |
| Mental disorder | _ | | Cirrhosis | 1. | - |
| Reduced libido | | | Abnormal liver function | 1. | |
| Paralysis | - | | tests | 1 | |
| Trismus | | | | ו | |
| Syncope | 3 | | Colitis | | |
| Cerebrovascular | (| | Dental caries | 1. | |
| disorders | | | Stomatitis | 1 | |
| Cerebral thrombosis | | | Diarrhoea | 3 | |
| Headache | 9 | | Dyspepsia | 1 | |
| Migrain | 3 | | Dysuria | 1 | |
| Sweating | 1 | | Vaginitis | 3 | |
| Cait disorder | 1 | | Urticaria | 3 | |
| Paraesthesia | 3 | | Erythema nodosum | 4 | |
| Retinal artery | | | Photosensitivity | 2 | - |
| thrombosis | 1 | | Eczema | 1 | |
| Visual disturbance | 1 | | Alopecia | 3 | |
| Vertigo | | | Hypertrichosis | 1 | 1. |
| Hypertension | 11 | | Pigment change | 2 | |
| Superficial venous | • | | Pruritus | 1 | |
| thrombosis | 26 | 1 | Other skin reactions | 2 | |
| Deep venous thrombosis | 34 | | Pregnancy while on | | • (|
| Thrombosis superior | 1 | | oral-contraceptives | 18 | |
| vena cava | 1 | | Arthralgia | 1 | |
| Venous thrombosis, site | | | Muscle pain | 5 | |
| not stated | 1 | | Sepsis | í | |
| Thrombophlebitis | 26 | | Cartinoma of breast | 1 | |
| | | | Cartinoma of cervix | 1 | |

Ethinyloestradiol (51010) with Megestol (52117)

'Nuvacon'

Total reports March 1964-December 1971 110 (4 fatal)

| | Total | Deaths |
|----------------------------------|-------|--------|
| Menorrhagia | 1 | |
| Amenorrhoea | 1 | |
| | 2 | |
| Break through bleeding | | |
| Oedema | 1 | |
| Emotional change | 1 | |
| Reduced libido | 1 | |
| Parkinsonism | 1 | |
| Syncope | 2 | |
| Cerebrovascular disorders | 6 | 1 |
| Cerebral thrombosis | 2 | |
| Headache | 1 | |
| Migraine | 5 | |
| Hypothermia | 1 | 1 |
| Paraesthesia | 1 | |
| Abnormal movements | 1 | |
| Visual disturbance | 2 | |
| Hypertension | 1 | |
| Superficial venous thrombosis | 11 | |
| Deep venous thrombosis | 11 | |
| Thrombophlebitis | 4 | |
| Pulmonary embolism | 10 | 1 |
| Thrombosis peripheral artery | 1 | |
| Vascular disorders | 2 | |
| Vasculitis | 1 | |
| Coronary occlusion | 2 | 1 |
| Chestpain | 1 | |
| Jaundice | 1 | |
| Diarrhoea | 1 | |
| Nausea and vomiting | 3 | |
| Urticaria | 3 | |
| Photosensitivity | í | |
| Alopecia | 4 | |
| Pigment change | 3 | |
| Other skin reaction | í | |
| Pregnancy, while on | | |
| oral-contraceptives | 16 | |
| Muscle pain | 3 | |
| Carcinoma of cervix | 1 | |
| CST.CTHOMS OF CGTATY *********** | | |

SEX HORMONES

Ethinyloestradiol (51010) with Ethisterone (52101)

'Amenorone', 'Amenorone Forte'

Total reports March 1964-December 1971 9 (1 fatal)

| | Total | Deaths |
|--------------------------|-------|--------|
| Convulsion | 1 | |
| Coronary occlusion | 1 | 1 |
| Congenital abnormalities | 6 | |
| Carcinoma of breast | 1 | |

SEX HORMONES

Ethinyloestradiol (51010) with Norethisterone (52103)

'Controvlar'

Total reports March 1964-December 1971 22 (4 fatal)

| | Total | Deaths |
|-------------------------------|-------|--------|
| Aplastic anaemia | 1 | 1 |
| Cerebral thrombosis | 1 | 1 |
| Headache | 1 | |
| Cerebrovascular disorders | 1 | |
| Generalised weakness | 1 | |
| Conjunctivitis | 1 | |
| Superficial venous thrombosis | 3 | |
| Deep venous thrombosis | 3 | |
| Pulmonary embolism | 6 | 1 |
| Thrombosis peripheral artery | 1 | |
| Coronary occlusion | 1 | 1 |
| Skin reactions | 2 | |

SEX HORMONES

Ethinyloestradiol (51010) with Dimethisterone (52105)

'Tova'

Total reports March 1964-December 1971 7

| | Total | Deaths |
|-------------------------------|-------|--------|
| Extrapyramidal symptoms | 1 | |
| Superficial venous thrombosis | 1 | |
| Deep venous thrombosis | 2 | |
| Pulmonary embolism | 1 | |
| Nausea and vomiting | 1 | |
| Muscle pain | 1 | |

Mestranol (51020) with Norethisterone (52103)

'Norinyl 1'

Total reports June 1968-December 1971 457 (11 fatal)

| | Total | Dea t h: | | otal | Deaths |
|--------------------------------|-------|-----------------|---------------------------------------|------|--------|
| Was a small a set a | | | Wasaanstnistian | 2 | |
| Menorrhagia | 1 | | Vasoconstriction | 13 | |
| Amenorrhoea | 19 | | Painful veins | 2 | |
| Breast hypertrophy | 9 | | Angina | 5 | 3 |
| Break-through bleeding | 12 | | Coronary occlusion | 4 | |
| Weight gain | 13 | | Chest pain | | |
| Oedema | 2 | | Oeddem of upper respiratory | 1 | |
| Aplastic anaemia | 1 | | tract | 2 | |
| Coagulation defect | 1 | | Dyspnoea | 5 | |
| Depression | 25 | | Jaundice | | |
| Emotional change | 3 | | Abnormal liver function | 3 | |
| Debility | 1 | | tests | 1 | |
| Reduced libido | 16 | | Dysphagia | 1 | |
| Neuropathy | 1 | | Increased appetite | 1 | |
| Convulsion | 1 | | Diarrhoea | 4 | |
| Syncope | 2 | | Nausea and vomiting | 1 | |
| Cerebrovascular disorders | 10 | | Abdominal pain | 3 | |
| Cerebral thrombosis | 8 | 2 | Vaginitis | í | |
| Headache | 16 | | Cervical (uterine) polyps | 2 | |
| Migraine | 7 | | Urticaria | 1 | |
| Sweating | 1 | | Angineurotic oedema | 2 | |
| Generalised weakness | 1 | | Purpura | 4 | |
| Paraesthesia | 1 | | Erythema nodosum | 5 | |
| Sensory disturbance | 1 | | Photosensitivity | 1 | |
| Giddiness | 2 | | Eczema | 2 | |
| Retinitis | 1 | | Alopecia | 2 | |
| Conjunctivitis | 1 | | Hypertrichosis | _ | |
| Glaucoma | 1 | | Pigment change | 9 | |
| Retinal artery thrombosis | 1 | | Moniliasis | _ | |
| Visual disturbance | 2 | | Pruritus | 2 | |
| Vertigo | 1 | | Other skin reactions | 7 | |
| Hypertension | 22 | | Congenital abnormalities | 2 | |
| Superficial venous thrombosis. | | | Pregnancy while on | | |
| Deep venous thrombosis | | 1 | oral-contraceptives | 31 | |
| * | | 1 | · · · · · · · · · · · · · · · · · · · | 4 | |
| Thrombophlebitis | | | Arthralgia | , | |
| Pulmonary embolism | | 4 | Muscle pain | ada. | |
| Budd-Chiari Syndrome | . 1 | 1 | Carcinoma of cervix | • | |

Mestranol (51020) with Norethisterone (52103)

Norinyl 2

Total reports December 1968-December 1971 6

| | Total | Deaths |
|-------------------------------|-------|--------|
| Superficial venous thrombosis | 2 | |
| Dental caries | 1 | |
| Pregnancy while on | | |
| oral-contraceptives | 2 | |
| Muscle pain | 1 | |

Mestranol (51020) with Norethisterone (52103)

Ortho-Novin 2mg*

Total reports March 1964-December 1971 258 (8 fatal)

| Т | otal. | Deaths | | Total | Deaths |
|-------------------------------|-------|--------|--------------------------|-------|--------|
| Menorrhagia | 1 | | Vasoconstriction | 1 | |
| Amenorrhoea | 3 | | Vasculitis | 1 | |
| Lactation | 1 | | Painful veins | 2 | |
| Dysmenorrhoea | 1 | | Angina | 2 | |
| Diabetes mellitus | 1 | | Coronary occlusion | 5 | .2 |
| Weightgain | .3 | | Chestpain | 6 | ~ |
| Oedema | 3 | | Dyspnoea | 1. | |
| Hyperlipaemia | 1 | | Asthma | 1 | |
| Thrombocytopenia | 1 | | Jaundice | 6 | |
| Depression | 11 | | Abnormal liver function | | |
| Debility | 1 | | tests | 1 | |
| Reduced libido | 2 | | Colitis | 1 | |
| Neuritis | 1 | | Gingivitis | 1 | |
| Paralysis | 1 | | Abdominal pain | 3 | |
| Cerebrovascular disorders | 6 | | Albuminuria | í | |
| Subarachnoid haemorrhage | 2 | 1 | Dysuria | 1 | |
| Cerebral thrombosis | 9 | | Vaginitis | 1 | |
| Headache | 7 | | Purpura | 2 | |
| Nigraine | 8 | | Morbilliform rash | 1 | |
| Anaesthesia | 1 | | Erythema nodosum | 2 | |
| Paraesthesia | 3 | | Photosensitivity | 1 | |
| Sleep disorder | 1. | | Alopecia | 4 | |
| Abnormal movements | 1 | | Pigmont change | 7 | |
| Retinitis | 1 | | Other skin reactions | 7 | |
| Cornea | 1 | | Congenital abnormalities | 2 | |
| Visual disturbance | 3 | | Pregnancy while on | | |
| Diplopia | 1 | | oral-contraceptives | 4 | |
| Hypertension | 8 | | Anaphylaxis | 1 | |
| Superficial venous thrombosis | 20 | | A thralgia | 1 | |
| Deep venous thrombosis | 25 | | Muscle pain | 2 | |
| Thrombosis portal vein | 2 | 1 | Reaction after alcohol | | |
| Thrombophlebitis | 22 | 4 | Sepsis | 1 | |
| Pulmonary embolism | 32 | 4 | Carcinoma of breast | . 4 | |

Mestranol (51020) with Norethisterone (52103)

'Ortho-Novin 1/80'

Total reports 1 irch 1964-December 1971 57 (1 fatal)

| | Total | Deaths |
|-------------------------------|-------|--------|
| Amenorrhoea | 1 | |
| Breast hypertrophy | 4 | |
| Break-through bleeding | 2 | |
| Diabetes mellitus | 1 | |
| Weightgain | 1 | |
| Depression | 2 | |
| Mental disorder | 1 | |
| Reduced libido | 2 | |
| Convulsion | 1 | |
| Cerebral thrombosis | 2 | |
| Headache | 1 | |
| Migraine | 3 | |
| Optic neuritis | 1 | |
| Hypertension | 3 | |
| Superficial venous thrombosis | 6 | |
| Deep venous thrombosis | 4 | |
| Pulmonary embolism | 9 | 1 |
| Chestpain | 1 | |
| Jaundice | 1 | |
| Colitis | 1 | |
| Skin reactions | 4 | |
| Pregnancy while on | | |
| oral-contraceptives | 2 | |
| Arthralgia | 1 | |
| Carcinoma of breast | 2 | |
| Carcinoma of cervix | 1 | |

Mestranol (51020) with Norethisterone (52103)

Ortho-Movin 1/50

Total reports May 1967-December 1971 50

| | Total | Deaths |
|-------------------------------|-------|--------|
| Amenorrhoea | 1 | |
| Depression | 1 | |
| Syncope | 1 | |
| Cerebrovascular disorders | 1 | |
| Cerebral thrombosis | | |
| Headache | | |
| Paraesthesia | | |
| Visual disturbance | | |
| Hypertension | 4 | |
| Superficial venous thrombosis | 5 | |
| Deep venous thrombosis | 10 | |
| Thrombophlebitis | 2 | |
| Pulmenary embolism | 9 | |
| Dyspnoea | 1 | |
| Abdominal pain | 1 | |
| Skin reaction | 1 | |
| Pregnancy while on | | |
| oral-contraceptives | 2 | |
| Joint symptoms | 2 | |
| Sarcoid | 1 | |

Mestranol (51020) with Norethisterone (52103)

'Ortho-Novin SQ'

Total reports March 1964-December 1971 3

| | Total | Deaths |
|---------------------|-------|--------|
| Colitis | 1 | |
| oral-contraceptives | 2 | |

Mestranol (51020) with Lynoestrenol (52110)

'Lyndiol'

Total reports March 1964-December 1971 251 (15 fatal)

| | Total | Deaths | Total | Deaths |
|---------------------------|-------|--------------------------|-------|--------|
| Goitre | 1 | Deep venous thrombosis | 25 | 2 |
| Premenstrual tension | ī | Thrombosis, portal vein | 1 | 1 |
| Menorrhagia | 1 | Thrombophlebitis | 17 | _ |
| Menstrual irregularities | 1 | Pulmonary embolism | 30 | 7 |
| Amenorrhoea | 4 | Vasoconstriction | 1 | • |
| Breast hypertrophy | 1 | Painful veins | 1 | |
| Weightgain | 12 | Palpitations | 1 | |
| Weightloss | 2 | Angina | 2 | |
| Oedema | 2 | Coronary occlusion | 8 | 3 |
| Fluid retention | 2 | Chestpain | 4 | |
| Thrombocytopenia | 1 | Bronchospasm | 1 | |
| Depression | 8 | Dyspnoea | 1 | |
| Emotional change | 1 | Rhinitis | 1 | |
| Debility | 1 | Jaundice | 10 | |
| Reduced libido | 5 | Diarrhoea | 2 | |
| Neuritis | í | Nausea and vomiting | 2 | |
| Paralysis | 2 | Abdominal pain | 1 | |
| Syncope | 2 | Flatulence | 1 | |
| Cerebrovascular disorders | 8 | Urticaria | 3 | |
| Cerebral thrombosis | 16 | 1 Angioneurotic oedema | 2 | |
| Headache | 8 | Stevens Johnson Syndrone | 1 | 1 |
| Migraine | 2 | Erythema nodosum | 1 | |
| Gait disorder | 1 | Pigment change | 3 | |
| Sensory disturbance | 1 | Other skin reactions | 5 | |
| Abnormal movements | 1 | Congenital abnormalities | í | |
| Giddiness | 1 | Pregnancy while on | | |
| Visual disturbance | 1 | oral-contraceptives | 6 | |
| Labyrinthitis | 1 | Muscle pain | 5 | |
| Hypertension | 7 | Carcinoma of breast | 2 | |
| Superficial venous | | Carcinoma of cervix | 1 | |
| thrombosis | 16 | Corcinoma | 1 | |

Mestranol (51020) with Lynoestrenol (52110)

'Lyndiol 2.5mg'

Total reports March 1964-December 1971 421 (11 fatal)

| | Total | Deaths | | Total | Deaths |
|---------------------------------|-------|--------|------------------------------|-------|--------|
| Hyperthyroidism | 3 | 7 | hrombosis, peripheral arter | y . 1 | 1 |
| Hypoadrenocorticism | 1 | 7 | asoconstriction | 1 | |
| Menorrhagia | 2 | | angrene | | |
| Menstrual irregularities | 5 | F | ainful veins | 4 | |
| Amenorrhoea | | | ngina | | |
| Breast hypertrophy | | | oronary occlusion | | 2 |
| Dysmenorrhoea | | | hestpain | | |
| Break-through bleeding | | | ronchospasm | | |
| Diabetes mellitus | | | yspnoea | | |
| Weightgain | | F | hinitis | 2 | |
| Oedema | 6 | Е | pistaxis | 2 | |
| Hypochromic anaemia | 1 | | espiratory symptoms | | |
| Depression | 26 | J | aundice | 7 | |
| Emotional change | 2 | | ingivitis | | |
| Mental disorder | 3 | S | tomatitis | 2 | |
| Reduced libido | 16 | | astro-intestinal haemorrhage | | |
| Encephalitis | 1 | N | ausea and vomiting | 5 | |
| Somnolence | 1 | | bdominal pain | | |
| Cerebrovascular disorders | 9 | V | aginitis | 3 | |
| Cerebral thrombosis | 8 | | rticaria | | |
| Headache | 16 | | urpura | | |
| Migraine | 9 | | rythema nodosum | | |
| Flushing | í | | hotosensitivity | | |
| Localised involuntary muscle | | | lopecia | | |
| spasm | 1 | | igment change | | |
| Paraesthesia | 3 | | ruritus | | |
| Sensory disturbance | 1 | | cne | | |
| Sleep disorder | 1 | | ther skin reactions | | |
| Abnormal movements | 2 | | ongenital abnormality | | |
| Ciddiness | 1 | | regnancy while on | | |
| Cataract | 1 | | oral-contraceptives | . 11 | |
| Visual disturbance | 2 | A | rthralgia | | ~ |
| Hypertension | 20 | | uscle pain | | |
| Superficial venous thrombosis . | 28 | Re | eaction after alcohol | . 1 | |
| Deep venous thrombosis | 40 | | epsis | | |
| Thrombophlebitis | 20 | | arcinoma of cervix | | |
| Pulmonary embolism | 46 | | arcinoma site unspecified | | |
| | | | | | |

Mestranol (51020) with Lynoestrenol (52110)

Ovanon !

Total reports March 1964-December 1971 1

Mestranol (51020) with Lynoestrenol (52110)

'Noracyclin'

| Total | reports | March | 196 | 4-Dece | ember | 1971 | 1 |
|-------|---------|-------|-----|--------|-------|------|---|
| | | | | | | | |

| | Total | Deaths |
|--------------------|-------|--------|
| Breast hypertrophy | 1 | |

Mestranol (51020) with Norethynodrel (52108)

Conovid

Total reports March 1964-December 1971 30 (5 fatal)

| | Total | Deaths |
|-------------------------------|-------|--------|
| Weightgain | 1 | |
| Cerebrovascular disorders | 1 | |
| Cerebral thrombosis | 3 | 1. |
| Optic haemorrhage | 1 | |
| Superficial venous thrombosis | 2 | |
| Deep venous thrombosis | 6 | |
| Thrombophlebitis | 2 | |
| Pulmonary embolism | 7 | 3 |
| Coronary occlusion | 3 | 1 |
| Skin reactions | 2 | |
| Carcinoma of breast | 2 | |

Mestranol (51020) with Norethynodrel (52108)

Conovid E

Total reports March 1964-December 1971 137 (10 fatal)

| | Total | Deaths | | Total | Deaths |
|--|-------|--------|--------------|---|--------|
| Menstrual irregularities Lactation Breast hypertrophy Break-through bleeding Weightgain Weightloss Oedema Haemolytic anaemia Hypochromic anaemia Mental symptoms following withdrawal Reduced libido Neuritis Paralysis Convulsion Cerebrovascular disorders Subarachnoid haemorrhage Cerebral thrombosis Headache Migraine Anaesthesia Paraesthesia Abnormal movements Cornea | | . 1 | Hypertension | 8 16 8 22 4 1 1 5 1 2 1 1 2 1 1 1 1 1 1 1 1 | 5 3 |
| Visual disturbance | . 1 | | | | |

Mestranol (51020) with Norethynodrel (52108)

'Previson'

Total reports March 1964-December 1971 13 (1 fatal)

| | Total | Deaths |
|-------------------------------|-------|--------|
| Cerebrovascular disorders | 1. | |
| Superficial venous thrombosis | 1 | |
| Pulmonary embolism | 3 | 1 |
| Thrombosis, peripheral artery | 1 | |
| Abnormal liver function tests | 1 | |
| Nausea and vomiting | 2 | |
| Skin reactions | 3 | |
| Carcinoma of cervix | 1 | |

Mestranol (51020) with Norethynodrel (52108)

Feminor 21

Total reports March 1964-December 1971 4

| | Total | Deaths |
|-------------------------------|-------|--------|
| Cerebral thrombosis | 1 | |
| Abnormal movements | 1 | |
| Superficial venous thrombosis | 1 | |
| Congenital abnormality | 1 | |

Mestranol (51020) with Norethynodrel (52108)

Feminor Seq

Total reports March 1964-December 1971 23

| | Total | Deaths |
|-------------------------------|-------|--------|
| Migraine | 2 | |
| Superficial venous thrombosis | 6 | |
| Deep venous thrombosis | 3 | |
| Thrombophlebitis | 1 | |
| Congenital abnormality | 1 | |
| Pregnancy while on | | |
| oral-contraceptives | 9 | |
| Arthralgia | 1 | |

Mestranol (51020) with Ethynodiol (52112)

Ovulen

Total reports March 1964-December 1971 873 (62 fatal)

| | Total | Deaths | | 1'otal 49 | Deaths |
|---|--------|--------|---|--------------|--------|
| Thyroid disorders | 1 | | Thrombophlebitis Intracranial venous | 49 | |
| Coitre | 2 | | thrombosis | 2 | |
| Hyperthyroidism | 1 | | Pulmonary embolism | 124 | 30 |
| Hypoadrenocorticism | 1 | 1 | Thrombosis, peripheral | | |
| Vaculitis due to steroids | 2 | | artery | 5 | |
| Premenstrual tension | 2 | | Vasoconstriction | 2 | |
| Menstrual irregularities | 8 | | Painful veins | 11 | |
| Amenorrhoea | 18 | | Arrhythmia | 1 | |
| Lactation | 2 | | Myocarditis | 1 | |
| Breast hypertrophy | 8 | | Angina | 2 | 26 |
| Break-through bleeding Androgenic effects | 3 1 | | Coronary occlusion | 30 1 | 16 |
| Pancreatic disorder | 1 | | Heart failure | 1 | , 1 |
| Diabetes mellitus | | | Chestpain | 12 | |
| Weightgain | | | Dyspnoea | 1 | |
| Oedema | 4 | | Asthma | 4 | 1 |
| Fluid retention | 2 | | Epistaxis | 3 | |
| Thrombocytopenia | 1 | | Jaundice | 19 | 1 . |
| Agranulocytosis | 1 | | Abnormal liver function | | |
| Psychosis | 1 | | tests | 2 | |
| Depression | 20 | | Colitis | 1 | |
| Mental symptoms | | | Dental caries | 1 | |
| following withdrawal | | | Gingivitis | 3 | |
| Emotional change | | | Stomatitis | 1 | |
| Mental disorder | | | Glossitis | 1 | |
| Debility | | | Gastro-intestinal | 1 | |
| Reduced libido | | | haemorrhage | 1 | |
| Neuritis | | | Diarrhoea | 4 | |
| Paralysis | | | Nausea and vomiting | 4 | |
| Trismus | | | Abdominal pain | 11 | |
| Oculogyric crisis | | | Ne phropathy | 1 | |
| Convulsion | . 2 | | Cervicitis | 3 | |
| Coma | . 1 | | Vaginitis | 3 | |
| Syncope | | | Urticaria | 2 | |
| Cerebrovascular disorder: | s 21 | | Purpura | . 5 | |
| Subarachnoid | • | 0 | Erythema multiforme | 1 | |
| haemorrhage | _ | 2 7 | Erythema nodosum | 4 | |
| Headache | | ′ | Photosensitivity | 2 | |
| | | | Eczema Tumour-like disorder of | 1 | |
| Migraine | . 14 | | the skin | 1 | |
| Paraesthesia | . 5 | | Alopecia | 6 | |
| Sensory disturbance | | | Hypertrichosis | 2 | |
| Stammer | | | Hair colour change | 1 | |
| Abnormal movements | . 2 | | Pigment change | 14 | |
| Giddiness | . 1 | | Vitiligo | 2 | |
| Optic neuritis | . 1 | | Pruritus | 3 | |
| Retinitis | • 3 | | Acne | 1 | |
| Cataract | . 1 | | Other skin reactions | 13 | |
| Papilloedema | . 1 | | Congenital abnormalities | . 2 | |
| Retinal artery thrombosis | s 1 | | Pregnancy while on | 10 | |
| Visual disburbance | • 3 | | oral contraceptives | 18 1 | |
| Blindness, | . 1 | | Anaphylactic shock Retroperitoneal fibrosis | | |
| Superficial venous | . 24 | .1 | Muscle pain | _ | |
| thrombosis | . 62 | | Carcinoma of breast | | |
| Deep venous thrombosis | | 2 | Carcinoma of cervix | 1. | |
| Thrombosis inferior | | | Carcinoma | 2 | |
| vena cava | . 1 | 1 | Tumour | 1 | |

Mestranol (51020) with Ethynodiol (52112)

Demulen!

Total reports April 1969-December 1971 13 (1 fatal)

| | Total | Deaths |
|-------------------------------|-------|--------|
| Depression | 1 | |
| Cerebrovascular disorders | 3 | 1 |
| Optic neuritis | 1 | |
| Superficial venous thrombosis | 2 | |
| Deep venous thrombosis | 4 | |
| Coronary occlusion | 1 | |
| Gingivitis | 1 | |



Mestranol (51020) with Chlormadinone (52115)

1Sequens1

Total reports March 1964-December 1971 111 (6 fatal)

| | Total | Deaths |
|-------------------------------|-------|--------|
| Menorrhagia | 1 | |
| Menstrual irregularities | 2 | |
| Amenorrhoea | 1 | |
| Breast hypertrophy | 1 | |
| Diabetes mellitus | 1 | |
| Weightgain | 1 | |
| Weightloss | 1 | |
| Schizophrenia | 1 | |
| Depression | 1 | |
| Neuritis | 2 | |
| Convulsion | 1 | |
| Cerebrovascular disorders | 2 | |
| Cerebral thrombosis | 4 | |
| Headache | 2 | |
| Migraine | 2 | |
| Giddiness | 1 | |
| Retinitis | 1 | |
| Optic haemorrhage | 1 | |
| Retinal vein thrombosis | 1 | |
| Superficial venous thrombosis | 2 | |
| Deep venous thrombosis | 9 | |
| Thrombo phlebitis | 2 | |
| Pulmonary embolism | 16 | 5 |
| Thrombosis, peripheral artery | 1 | í |
| Vasoconstriction | 1 | _ |
| Coronary occlusion | 1 | |
| Jaundice | 3 | |
| Salivary gland swelling | 1 | |
| Mausea and vomiting | 1 | |
| Me phropathy | 1 | |
| Vaginitis | 3 | |
| Skin reactions | 4 | |
| Congenital abnormality | 1 | |
| Pregnancy while on | 1 | |
| oral-contraceptives | 36 | |
| irthralgia | 5 | |
| Muscle pain | 2 | |
| 100000 | ۲. | |

Mestranol (51020) with Chlormadinone (52115)

C-Quens 21

Total reports March 1964-December 1971 64 (4 fatal)

| | Total | Deaths |
|--|-------|--------|
| The state of the s | , | |
| Breast hypertrophy | 1 | |
| Weightgain | 1 | |
| Reduced libido | 1 | |
| Sommolence | 1 | |
| Cerebral thrombosis | 1 | |
| Headache | 2 | |
| Superficial venous thrombosis | 1 | |
| Deep venous thrombosis | 6 | 1 |
| Pulmonary embolism | 9 | 1 |
| Thrombosis peripheral artery | 1 | |
| Budd-Chiari Syndrome | 1 | 1 |
| Coronary occlusion | 1 | |
| Heart failure | 1 | 1 |
| Gastro-intestinal haemorrhage | 1 | |
| Nausea and vomiting | 1 | |
| Vaginitis | 1 | |
| Skin reactions | 3 | |
| Pregnancy while on | | |
| oral-contraceptives | 30 | |
| Muscle pain | 1 | |

Mestranol (51020) with Ethynodiol (52112)

'Metrulen'

Total reports March 1964-December 1971 42 (7 fatal)

| | Total | Deaths |
|-------------------------------|-------|--------|
| Menstrual irregularities | 1 | |
| Cerebral thrombosis | 4 | 3 |
| Superficial venous thrombosis | 10 | |
| Deep venous thrombosis | 5 | |
| Thrombophlebitis | 4 | |
| Pulmonary embolism | 13 | 3 |
| Dyspnoea | 1 | |
| Haemoptysis | 1 | |
| Jaundice | 1 | 1 |
| Skin reaction | 1 | |
| Pregnancy while on | | |
| oral-contraceptives | 1 | |

Mestranol (51020) with Ethynodiol (52112)

'Metrulen M'

Total reports Narch 1964-December 1971 63 (7 fatal)

| | Total | Deaths |
|-------------------------------|-------|--------|
| | | |
| Menstrual irregularities | 1 | |
| Breast hypertrophy | 1 | |
| Weightgain | 1 | |
| Depression | 2. | |
| Mental disorder | 1 | |
| Convulsions | 2 | |
| Cerebral thrombosis | 4 | 3. |
| Headache | 3 | |
| Migraine | 1 | |
| Retinitis | 1 | |
| Visual disturbance | 2 | |
| Superficial venous thrombosis | 8 | |
| Deep venous thrombosis | 12 | |
| Thrombophlebitis | 2 | |
| Pulmonary embolism | 10 | 2 |
| Coronary occlusion | 4 | 4 |
| Chestpain | 1 | |
| Epistaxis | 1 | |
| Skin reactions | 2 | |
| Pregnancy while on | | |
| oral-contraceptives | 3 | |
| Carcinoma of cervix | 1 | |
| | | |

Mestranol (51020) with Norethynodrel (52108)

'Enavid'

Total reports March 1964-December 1971 62 (10 fatal)

| | Total | Deaths |
|-------------------------------|-------|--------|
| Thrombocytopenia | 2 | |
| Depression | 1 | |
| Subarachnoid haemorrhage | 1 | |
| Cerebral thrombosis | 4 | |
| Migraine | 1 | |
| Vertigo | 1 | |
| Hypertension | 1 | |
| Superficial venous thrombosis | 4 | |
| Deep venous thrombosis | 11 | |
| Thrombophlebitis | 3 | |
| Pulmonary embolism | 22 | 9 |
| Thrombosis peripheral artery | 2 | |
| Chestpain | 1 | 1 |
| Jaundice | 2 | |
| Cervical (uterine) polyps | 1 | |
| Skin reactions | 2 | |
| Congerital abnormalities | 2 | |
| Carcinoma of breast | -1 | |

Mestranol (51020) with Norethynodrel (52108)

Enavid E

Total reports Harch 1964 - December 1971 8

| T | otal | Deaths |
|-------------------------------|------|--------|
| Cerebral thrombosis | 1 | |
| Retinitis | 1 | |
| Superficial venous thrombosis | 2 | |
| Deep venous thrombosis | 1 | |
| Pulmonary embolism | 3 | • |

Oestrogens unspecified (51999) with

Progestogens unspecified (52999)

Total recorts March 1964-December 1971 277 (56 fatal)

| Tot | al Deaths | . Т | otal | Deaths |
|---|----------------------------|--|-----------------------|--------|
| Goitre Potentiation of infection by adrenal steroids | 1 | Thrombophlebitis | 60 | 29 |
| Menstrual irregularities | 3 | Thrombosis peripheral artery Budd-Chiari Syndrome | 2 | 2 |
| Amenorrhoea | 3 | Painful veins | 3 1 1 | 1 |
| Weightgain Oedema Fluid retention Depression | 2 3 2 9 | Angina | 14 3 1 5 | 13 |
| Hallucinations Reduced libido Convulsion Cerebrovascular disorders Subarachnoid haemorrhage Cerebral thrombosis | 1 1 | Abnormal liver function tests Dental caries Gingivitis Diarrhoea Nausea and vomiting | 1 1 2 1 2 | |
| Headache Migraine Paraesthesia Sensory disturbance Abnormal movements Conjunctivitis Scleritis | 6 9 1 3 1 2 | Dysuria Urticaria Purpura Erythema nodosum Fixed drug eruption | 2 | 1 |
| Cornea | 1 3 1 1 1 1 | Alopecia | 3 1 1 2 2 | |
| Hypertension | 11 10 | Pregnancy while on oral-contraceptives Carcinoma of breast Carcinoma of cervix | . 1 | |

Testosterone (53001)

'Neobombreol', 'Primoteston Depot', 'Sustanon', 'Tess PP', Testoral'

Total reports February 1965-October 1971 2 (1 fatal)
Reports not listed Nil

| | Total | Deaths |
|--------------------|-------|--------|
| Pulmonary embolism | . 1 | |
| Coronary occlusion | . 1 | 1 |

| Prescriptions | (EC 10) | for | 1968 | 11,000 |
|---------------|---------|-----|------|--------|
| n | 11 | 11 | 1969 | 12,000 |
| tt | 11 | 11 | 1970 | 22,000 |

Androsterone (53010)

Total reports March 1964-October 1971 4 Reports not listed 1

| | Tota1 | Deaths |
|--------------|-------|--------|
| Alopecia | 1 | |
| Nail changes | 1 | |
| Pruritus | 1 | |

Fluoxymesterone (53030)

'Ultandren'

Total reports November 1969-October 1971 1
Reports not listed Nil

Jaundice 1

| Prescriptions | (EC 10) | for | 1968 | 8,000 |
|---------------|---------|-----|------|--------|
| н | tt | 11 | 1969 | 9,000 |
| п | 68 | π | 1970 | 10,000 |

*Methyltestosterone (53101)

'Micryston Testosterone', 'Perandren'

Total reports September 1964-October 1971 5 (1 fatal) Reports not listed Nil

| | Total | Deaths |
|-------------------------------|-------|--------|
| Androgenic effects | 1 | |
| Oedema | 1 | |
| Somnolence | 1 | |
| Superficial venous thrombosis | 1 | |
| Jaundice | 3 | 1 1 |
| Mucous membrane change | 1 | |

*Not combined with other hormone

Nandrolone (54005)

'Durabolin'

Total reports June 1965-October 1971 10 (1 fatal) Reports not listed 2

| | Total | Deaths |
|---------------|------------------|--------|
| Oedema | 1 2 2 1 | 1 |
| Skin reaction | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 59,000 |
|---------------|---------|-----|------|--------|
| Н | 19 | 17 | 1969 | 57,000 |
| nt | 11 | 11 | 1970 | 62,000 |

Norethandrolone (54008)

'Nilevar'

Total reports February 1969-October 1971 1
Reports not listed Nil

Prescriptions (EC 10) for 1968 5,000

" " 1969 5,000

" " 1970 4,000

Methandienone (54010)

'Dianabol'

Total reports July 1964-October 1971 6 Reports not listed 1

| | Total | Deaths |
|-------------------|------------------|--------|
| Diabetes mellitus | 1 1 1 1 | |
| Sepsis | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 23,000 |
|---------------|---------|-----|------|--------|
| Ħ | 11 | 11 | 1969 | 23,000 |
| 19 | П | н | 1970 | 18,000 |

Stanazolol (54020)

Stromba

Total reports June 1964-October 1971 4 Reports not listed 1

| | Tota1 | Deaths |
|------------|-------------|--------|
| Leucopenia | 1 1 1 | |

| Prescriptions | (EC | 10) | for | 1968 | 105,000 |
|---------------|-----|-----|-----|------|---------|
| н | n | | Ħ | 1969 | 97,000 |
| Ħ | 11 | | 19 | 1970 | 106,000 |

Ethyloestrenol (54030)

'Orabolin'

Total reports June 1968-October 1971 3 Reports not listed 1

| | Total | Deaths |
|----------|-------|--------|
| Jaundice | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 18,000 |
|---------------|---------|-----|------|--------|
| H | n | n | 1969 | 16,000 |
| 17 | IT | 11 | 1970 | 16,000 |

Oxymetholone (54050)

'Adroyd', 'anapolon'

Total reports May 1969-October 1971 21 (5 fatal) Reports not listed 4

| | Tota1 | Deaths |
|--------------------|-------|--------|
| Oedema | 1 | |
| Fluid retention | 2 | |
| Aplastic anaemia | 1 | 1 |
| Coagulation defect | 2 | |
| Leukaemia | 3 | 2 |
| Cataract | 1 | 1 |
| Heart Failure | 1 | |
| Epistaxis | 1 | |
| Jaundice | 3 | 1 |
| Diarrhoea | 1 | |
| Skin reaction | 1 1 | |

| Prescriptions | (EC 10) | for | 1968 | 5,000 |
|---------------|---------|-----|------|-------|
| 11 | tř | 11 | 1969 | 3,000 |
| 19 | FT . | 11 | 1970 | 6,000 |

Cortisone (55101)

'Adreson', 'Cortelan', 'Cortistab', 'Cortisyl'

 Total reports August 1964-October 1971
 26 (16 fatal)

 Reports not listed
 5 (2 fatal)

| | Total | Deaths |
|----------------------------------|-------|--------|
| Hypoadrenocorticism | 4 | 3 |
| Conjunctivitis | 1 | |
| Heart failure | 1 | 1 |
| Gastric ulcer with haemorrhage . | 2 | 2. |
| Nausea and vomiting | 1 | |
| Intestinal perforation | 4 | 4 |
| Gastro-intestinal haemorrhage | 5 | 4 |
| Angioneurotic oedema | 1 | |
| Congenital abnormalities | 2 | |

| Prescriptions | (EC 10) | for | 1968 | 67,000 |
|---------------|---------|-----|------|--------|
| 11 | п | n | 1969 | 66,000 |
| 11 | 11 | 11 | 1970 | 62,000 |

Prednisone (55103)

'Co-deltra', 'Decortisyl', 'Delta-Butazolidin', 'Delta-cortelan'
'Deltacortone', 'Di-Adreson', 'Elestol'

Total reports May 1964-October 1971 135 (52 fatal) Reports not listed 70 (26 fatal)

| | Total | Deaths | 3 | Total | Deaths |
|--------------------------------|-------|--------|---------------------------------|-------|--------|
| Hypothyroidism | 1 | | Asthma | 2 | 2 |
| Potentiation of infection | | | Peptic ulcer | 2 | 2 |
| by adrenal steroids | 1 | 1 | Gastric ulcer with haemorrhage | 2 | 2 |
| Osteoporosis due to steroids . | 1 | | Gastric ulcer with perforation | 3 | 3 |
| Diabetes mellitus | 3 | | Duodenal ulcer with haemorrhage | 2 | 2 |
| Oedema | 1 | | Duodenal ulcer with perforation | 1 | -1 |
| Aplastic anaemia | 1 | 1 | Intestinal perforation | 2 | 2 |
| Hypochromic anaemia | 1 | | Stomatitis | 1 | |
| Depression | 2 | | Dysphagia | 1 | |
| Dependence | 1 | | Gastro-intestinal haemorrhage . | 5. | 2 |
| Aggravation of pre-existing | | | Ileus | 2 | 1 |
| psychiatric disorder | 1 | | Abdominal pain | 1 | 1 |
| Neuritis | 1.1 | | Urticaria | 1 | |
| Somnolence | ľ | | Photosensitivity | 3 | |
| Cerebral thrombosis | 1 | | Eczema | | |
| Paraesthesia | 1 | | Alopecia | 1 | |
| Visual disturbance | 1 | | Other skin reactions | 2 | |
| Hypertension | 1 | | Hydrocephalus | 1 | |
| Thrombosis inferior vena cava | 1 | | Mongolism | | |
| Thrombosis | 1 | | Cleft-palate | | |
| Cardiac arrest | 2 | 2 | Congenital abnormalities | | |
| Coronary occlusion | 1 | 1 | of intestines | 1 | |
| Heart failure | 2 | 2 | Anaphylactic shock | 1 | |
| Bronchospasm | 1 | 1 | Pyrexia | | |

| Prescriptions | (EC 10) | for | 1968 | 1,719,000 |
|---------------|---------|-----|------|-----------|
| 19. | П | 11 | 1969 | 1,688,000 |
| | 11 | 11 | 1970 | 1,833,000 |

Hydrocortisone (55201)

Total eports May 1964-October 1971 60 (6 fatal) Reports not listed 15 (1 fatal)

| | Total | Deaths |
|---------------------------------|-------|--------|
| Pancreatic disorder | 1 | |
| Oedema | 1 | |
| Convulsions | 1 | |
| Syncope | 2 | |
| Paraesthesia | 12 | |
| Stammer | 1 | |
| Taste abnormality | 1 | • |
| Cardiac arrest | 2 | 2 |
| Duodenal ulcer with perforation | 1 | 1 |
| Intestinal perforation | 1 | 1 |
| Gastro-intestinal haemorrhage | 1 | 1 |
| Nausea and vomiting | 1 | |
| Urticaria | 2 | |
| Eczema | | |
| Contact dermatitis | 3 | |
| Skin, localised reaction | 1 | |
| Other skin reactions | 2 | |
| Anaphylaxis | 1 | |
| Arthralgia | 10 | |

| Prescriptions | (EC 10) | for | 1968 | 3,138,000 |
|---------------|---------|-----|------|-----------|
| 11 | | | 1969 | 3,362,000 |
| 31 | 11 | 11 | 1970 | 4.413.000 |

Prednisolone (55203)

Total reports May 1964-October 1971 194 (58 fatal) Reports not listed 94 (21 fatal)

| | Total | Deaths | | Total | Deaths |
|---------------------|--|-----------------|--|--|---|
| Adrenal hyperplasia | Total 1 9 3 2 1 1 3 3 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | Deaths 1 6 3 1 | Hypertension Pulmonary embolism Cardiac arrest Coronary occlusion Heart failure Bronchospasm Peptic ulcer Gastric ulcer with haemorrhage Gastric ulcer with perforation Duodenal ulcer Duodenal ulcer with haemorrhage Gastro-intestinal haemorrhage Diarrhoea Nausea and vomiting Nocturia Urticaria Tumour-like disorder of the skin Alopecia Other skin reactions Congenital abnormality Anaphylaxis Pyrexia Muscle pain Sepsis Atrophy following | Total 2 2 1 6 2 3 4 1 2 5 3 2 1 1 2 1 1 1 | Deaths 1 2 1 6 1 1 2 2 2 1 1 1 1 1 1 1 1 1 1 |
| | | | intra-muscular injection | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 534,000 |
|---------------|---------|-----|------|---------|
| н | 11 | 11 | 1969 | 508,000 |
| 11 | 11 | 11 | 1970 | 488,000 |

Methylprednisolone (55205)

'Depo-Medrone', 'Medro-Cordex', 'Medrone', 'Neo-Medrone'

Total reports June 1964-October 1971 26 (2 fatal) Reports not listed 5

| | Total | Deaths |
|---------------------------|-------|--------|
| Potentiation of infection | | |
| by adrenal steroids | 1 | 1 |
| Psychosis | 1 | |
| Headache | 1 | |
| Cataract | 2 | |
| Hypotension | 1 | |
| Deep venous thrombosis | 1 | |
| Heart failure | 1 | 1 |
| Dysuria | 1 | |
| Skin reactions | 3 | |
| Atrophy following | | |
| Subcutaneous injection | 3 | |
| Atrophy following | | |
| Intra-muscular injection | 5 | |
| Necrosis following | | |
| Intra-muscular injection | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 643,000 |
|---------------|---------|-----|------|---------|
| Ħ | | | | 637,000 |
| 11 | H | 11 | 1970 | 646,000 |

Dexamethasone (55207)

'Decadron', 'Decaspray', 'Dexacortisyl', 'Dexa-Rhinaspray'
'Oradexon', 'Perideca', 'Sofradex', 'Vasodex'

Total reports October 1964-October 1971 5 (2 fatal) Reports not listed 1

| | Total | Deaths |
|------------------|-------|--------|
| Thrombocytopenia | 1 | 1 |
| Headache | 1 | |
| Tachycardia | 1 | |
| Peptic ulcer | 1 | 1 |

Betamethasone (55209)

'Betnelan', 'Betnesol', 'Betnovate'

Total reports March 1964-October 1971 45 (9 fatal) Reports not listed 12 (2 fatal)

| | Total | Deaths |
|---|-------|--------|
| Adrenal hyperplasia | 1 | |
| Hypoadrenocorticism | 1 | 1 |
| Oedema | | 1 |
| Syncope | 1 | |
| Generalised weakness | 1 | |
| Stammer | 1 | |
| Glaucoma | 1 | |
| Visual disturbance | 2 | |
| Nerve deafness | | |
| Pulmonary embolism | 1 | 1 |
| Cardiac arrest | 1 | 1 |
| Coronary occlusion | 1 | 1 |
| Jaundice | 1 | |
| Peptic ulcer | 1 | 1 |
| Intestinal perforation | 1 | 1 |
| Gastro-intestinal haemorrhage | 1 | |
| Urticaria | 3 | |
| Photosensitivity | í | |
| Contact dermatitis | | |
| Ichthyosis | | |
| Skin, localised reaction | 4 | |
| Other skin reactions | 5 | |
| OHIOT PRETIL TOROUTORD \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ | | |

| Prescriptions | (EC 10) | for | 1968 | 5,144,000 |
|---------------|---------|-----|------|-----------|
| 11 | п | 11 | 1969 | 5,514,000 |
| 11 | 11 | 11 | 1970 | 5,639,000 |

Triamcinolone (55212)

'Adcortyl', 'Aureocort', 'Kenalog', 'Ledercort'
'Remotic', 'Remiderm', 'Tri-Adcortyl'

Total reports October 1964-October 1971 22 (3 fatal)

Reports not listed 10 (2 fatal)

| | Total | Deaths |
|--------------------------|-------|--------|
| Nerve deafness | 1 | |
| Hypertension | 1 | 1 |
| Skin reactions | 2 | |
| Anaphylactic shock | 1 | |
| Anaphylaxis | 1 | |
| Atrophy following | | |
| Intra-dermal injection | 1 | |
| Necrosis following | | |
| Subcutaneous injection | 1 | |
| Atrophy following | | |
| Intra-muscular injection | 4 | |

| Prescriptions | (EC 10) | for | 1968 | 794,000 |
|---------------|---------|-----|------|---------|
| н | 11 | п | 1969 | 686,000 |
| H | 19 | 17 | 1970 | 998,000 |

Paramethasone (55215)

'Haldrate', 'Metilar'

 Total reports June 1967-October 1971
 2

 Reports not listed
 Nil

| | Total | Deaths |
|------------------|-------|--------|
| Thrombocytopenia | 1 | |
| Cataract | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 5,000 |
|---------------|---------|-----|------|-------|
| н | | | 1969 | 9,000 |
| 13 | 11 | 11 | 1970 | 6,000 |

Flumethasone Pivalate (55230)

'Locorten'

Total reports April 1965-October 1971 3
Reports not listed 1

Total Deaths
Skin reactions 2

| Prescriptions | (EC 10) | for | 1968 | 149,000 |
|---------------|---------|-----|------|---------|
| п | U | 11 | 1969 | 137,000 |
| 11 | 13 | Ħ | 1970 | 117,000 |

Fluocinolone (55235)

'Synandone', 'Synalar'

Total reports August 1966-October 1971 7 Reports not listed 2

| | Total | Deaths |
|----------------------------|-------|--------|
| Hypoadrenocorticism | 1 | |
| Deep venous thrombosis | 1 | |
| Vascular disorders | 1 | |
| Necrosis of skin, not from | | |
| injection | 1 | |
| Hair colour change | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 2,331,000 |
|---------------|---------|-----|------|-----------|
| н | H | Ħ | 1969 | 2,104,000 |
| 11 | 97 | 17 | 1970 | 2,201,000 |

Flurandrenolone (55240)

'Drenison', 'Haelan'

Total reports March 1969-October 1971 3
Reports not listed Nil

Prescriptions (EC 10) for 1968 311,000

" " 1969 337,000

" " 1970 426,000

CORTICOSTEROIDS

Fludrocortisone (55245)

Florinef

Total reports September 1969-October 1971 2

Reports not listed Nil

| | Total | Deaths |
|----------------------|-------|--------|
| Hypoadrenocorticism | 1 | |
| Angioneurotic oedema | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 22,000 |
|---------------|---------|-----|------|--------|
| H | 11 | | 1969 | 21,000 |
| Н | H | 11 | 1970 | 20,000 |

Thyroxine (63001)

'Eltroxia'

Total reports August 1967-October 1971 49 (4 fatal)

Reports not listed 36 (4 fatal)

| | Total | Deaths |
|------------------------|-------|--------|
| Thrombocytopenia | 1 | |
| Mental disorder | 1 | |
| Convulsion | 1 | |
| Sweating | 1 | |
| Visual disturbance | 1 | |
| Vertigo | 2 | |
| Diarrhoea | 1 | |
| Nausea and vomiting | 1 | |
| Abortion | 1 | |
| Congenital abnormality | 2 | |
| Muscle pain | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 692,000 |
|---------------|---------|-----|------|---------|
| 17 | 11 | 11 | 1969 | 794.000 |
| H | 11 | 11 | 1970 | 875,000 |

Liothyronine (63003)

'Tertroxin'

Total reports July 1964-October 1971 3

Reports not listed 1

Total Deaths
Skin reactions 2

| Prescriptions | (EC 10) | for | 1968 | 8,000 |
|---------------|---------|-----|------|--------|
| n | ท | 11 | 1969 | 11,000 |
| Ħ | 17 | Ħ | 1970 | 12,000 |

Thyrold (63005)

'Elityran', 'Glandiposan', 'Thyrodex', 'Thyropit'

Total reports February 1965-October 1971 7 (3 fatal)

Reports not listed 6 (3 fatal)

Total Deaths

Tremor

| Prescriptions | (EC 10) | for | 1968 | 542,000 |
|---------------|---------|-----|------|---------|
| Ħ | II | 17 | 1969 | 495,000 |
| Ħ | п | tt | 1970 | 458,000 |

Thyrotrophin (63006)

'Thytropar'

Total reports September 1967-October 1971 1

Reports not listed Nil

Total Deaths
Anaphylaxis 1

Calcitonin (63008)

Total reports May 1969-October 1971 1 (1 fatal) Reports not listed Nil

| | | | Tota1 | Deaths |
|-------------|----------|--------|-------|--------|
| Pulmonary e | embolism | ****** | 1 | 1 |

Diiodotyrosine (63010)

Total reports January 1965-October 1971 2 Reports not listed Nil

| | Tota1 | Deaths |
|------------------|-------|--------|
| Emotional change | 1 | |
| Mental disorder | 1 | |

Propylthiouracil (63502)

| Total reports | November | 1964-00 | ctobe | r 1971 | |
|---------------|----------|---------|-------|--------|---|
| | F | Reports | | listed | 1 |

| | Total | Deaths |
|------------------------|-------|--------|
| Skin reaction | 1 | |
| Congenital abnormality | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 4,000 |
|---------------|---------|-----|------|-------|
| It | T! | п | 1969 | 2,000 |
| п | H | Ħ | 1970 | 3,000 |

Methylthiouracil (63503)

Total reports April 1965-December 1969 5 (2 fatal) Reports not listed 1

| | Total | Deaths |
|-----------------|-------|--------|
| Leucopania | 1 | |
| Agranulocytosis | 2 | 2 |
| Skin reaction | 1 | |

Carbimazole (63602)

'Neo-Mercazole'

Total reports May 1964-October 1971 81 (10 fatal) Reports not listed 8 (3 fatal)

| | Total | Deaths |
|-------------------------------|-------|--------|
| Eosinophilia | 2 | |
| Thrombocytopenia | 2 | |
| Leucopenia | 3 | |
| Agranulocytosis | 9 | 3 |
| Neutropenia | 1 | |
| Pancytopenia | 1 1 | 1 |
| Haemolytic anaemia | 1 | |
| Aplastic anaemia | 2 | 2 |
| Hypoplastic anaemia | 2 | |
| Macrocytic anaemia | 1 | |
| Encephalitis | - 1 | |
| Meuropathy | 1 | |
| Headache | 2 | |
| Spasticity | 1 | |
| Conjunctivitis | 1 | |
| Shock (not anaphylactic) | 1 | |
| Jaundice | 2 | 1 |
| Glossitis | 3 | |
| Nausea and vomiting | 1 | |
| Abdominal pain | 1 | |
| Abortion | 1 | |
| Urticaria | 5 | |
| Alopecia | 8 | |
| Hair colour change | 2 | |
| Other skin reactions | 4 | |
| Multiple congenital | · · · | |
| abnormalities | 2 | |
| Congenital spinal deformity | 1 | |
| Congenital abnormality of the | | |
| eye | 1 | |
| Cleft-palate | 1 | |
| Limb deformities | 1 | |
| Reduction deformity of limbs | 1 | |
| Congenital heart disease | 1 | |
| Oesophageal atresia | 1 | |
| Arthralgia | 3 | |
| Pyrexia | 1 | |
| Carcinoma of breast | 1 | |
| Carcinoma | 1 | |
| | - | |

| Prescriptions | (EC 10) | for 1968 | 156,000 |
|---------------|---------|----------|---------|
| ŤŤ. | 11 | " 1969 | 149,000 |
| 11 | 11 | " 1970 | 174,000 |

Potassium Parchlorate (63901)

'Peroidin'

Total reports March 1965-October 1971 3 (3 fatal)

Reports not listed 2 (2 fatal)

| | | | Total | |
|----------|---------|---|-------|---|
| Aplastic | anaemic | * | 1 | 1 |

Radio Active Iodine (63990)

Total reports April 1966-October 1971 2 Reports not listed Nil

| | Total | Deaths |
|------------------------|-------|--------|
| Congenital abnormality | 1 | |
| Carcinoma | 1 | |

Tolbutamide (64201)

'Artosin', 'Rastinon'

Total reports May 1964-October 1971 27 (2 fatal)
Reports not listed 8 (1 fatal)

27 (2 fatal)

| | Total | Deaths |
|---------------------------|-------|--------|
| Hypoglycaemia | 1 | |
| Fluid retention | 1 | |
| Aplastic anaemia | 1 | 1 |
| Hypoplastic anaemia | 1 | |
| Macrocytic anaemia | 1 | |
| Coagulation defect | 1 | |
| Coma | 1 | |
| Cerebrovascular disorders | 1 | |
| Flushing | 1 | |
| Jaundice | 2 | |
| Diarrhoea | 1 | |
| Lupoid reaction | 1 | |
| Eczema | 2 | |
| Pruritus | 1 | |
| Other skin reactions | 3 | |
| | | |

| Prescriptions | (EC 10) | for | 1968 | 316,000 |
|---------------|---------|-----|------|---------|
| 11 | 11 | n | 1969 | 324,000 |
| į II | 17 | 11 | 1970 | 324,000 |

Tolazamide (64202)

'Tolanase'

Total reports May 1968-October 1971 1
Reports not listed NIL

Total Deaths
Thrombocytopenia 1

 Prescriptions
 (EC 10)
 for 1968
 17,000

 "
 "
 " 1969
 20,000

 "
 "
 " 1970
 12,000

Chlorpropamide (64203)

†Diabinese†

Total reports June 1964-October 1971 98 (12 fatal) Reports not listed 13

| | Total | Deaths |
|-------------------------------|-------|--------|
| Breast hypertrophy (female) | 1 | |
| Excessive hypoglycaemia | 4 | 1 |
| Loss of control of diabetes | 1 | |
| Gout | 1 | |
| Thrombocytopenia | 8 | 1 |
| Leucopenia | 2 | |
| Agranulocytosis | 2 | |
| Neutropenia | 1 | |
| Pancytopenia | 1 | 1 |
| Haemolytic anaemia | 1 | 1 |
| Aplastic anaemia | 4 | 4 |
| Confusional state | 1 | |
| Hallucinations | 1 | |
| Convulsions | 1 | |
| Flushing | 1 | |
| Giddiness | 1 | |
| Visual disturbance | 1 | |
| Coronary occlusion | 1 | |
| Jaundice | 8 | 1 |
| Abnormal liver function tests | 4 | |
| Gastric ulcer | 1 | |
| Diarrhoea | 4 | |
| Purpura | 4 | 2 |
| Morbilliform rash | 1 | |
| Erythema multiforme | 2 | |
| Stevens Johnson Syndrome | 1 | |
| Erythema nodosum | 1 | |
| Exfoliative dermatitis | 1 | |
| Photosensitivity | 1 | |
| Eczema | 2 | |
| Alopecia | 1 | |
| Lichenoid | 1 | |
| Other skin reactions | 13 | |
| Intrauterine death | 1 | |
| Reaction after alcohol | 5 | |
| Overdose ., | 1 | |
| | | |

| Prescriptions | (EC 10) | for | 1968 | 530,000 |
|---------------|---------|-----|------|---------|
| 11 | Ħ | 11 | 1969 | 564,000 |
| II | п | 17 | 1970 | 592,000 |

Glibenclamide (64204)

'Daonil', 'Euglucon'

Total reports February 1970-October 1971 Reports not listed

| | Total | Death |
|---------------|-------|-------|
| Hypoglycaemia | 1 1 1 | |

Acetohexamide (64205)

Dimelor

Total reports January 1967-October 1971 2 (1 fatal) Reports not listed NII

| | Total | Deaths |
|------------------------|-------|--------|
| Neonatal hypoglycaemia | | |
| (mother treated) | | |
| Pancytopenia | 1 | 1 |
| | | |

| Prescriptions | (EC | 10) | for | 1968 | 13,000 |
|---------------|-----|-----|-----|------|--------|
| TI | 1 | | 11 | 1969 | 16,000 |
| п | Ħ | | 17 | 1970 | 32,000 |

Metformin (64304)

'Diguanil', 'Glucophage', 'Obin'

Total reports March 1965-October 1971 9 (2 fatal) Reports not listed 1

| | Total | Deaths |
|--------------------|-------|--------|
| Metosis | 1 | 1 |
| Sleep disorder | 1 | |
| Gastric ulcer | 1 | |
| Intrauterine death | 1 | 1 |

| Prescriptions | (EC 10) | for | 1968 | 47,000 |
|---------------|---------|-----|------|--------|
| II | | | | 54,000 |
| FT | 11 | Ħ | 1970 | 73,000 |

Phenformin (64305)

'Dibotin'

Total reports October 1964-October 1971 35 (5 fatal) Reports not listed 7

| | Tota1 | Deaths |
|----------------------|-------|--------|
| Oedema | | 3 |
| Thrombocytopenia | . 1 | |
| Macrocytic anaemia | . 1 | |
| Mental disorder | . 1 | |
| Coma | . 1 | 1 |
| Visual disturbance | | |
| Angina | | |
| Abdominal pain | | |
| Erythern multiforme | | |
| Other skin reactions | | 1 |
| | | |

| Prescriptions | (EC 10) | for | 1968 | 119,000 |
|---------------|---------|-----|------|---------|
| 11 | | | | 156,000 |
| 11 | 11 | 11 | 1970 | 179,000 |

Glymidine (64355)

Gondafon

Total reports September 1969-October 1971 1 Reports not listed NIL

| | | Total | Deaths |
|----------|-------|-------|--------|
| Diplopia | ••••• | 1 | |

Potassium Chloride (67901)

Total reports March 1964-October 1971 313 (26 fatal) Reports not listed 207 (11 fatal)

| | TotalDeaths | | Total | Deaths |
|---|-------------|--------------------------------|-------|--------|
| Gynaecomastia (Male) Diabetes mellitus Thrombocytopenia | 1 1 1 | Gastric ulcer with haemorrhage | . 1 | 1 |
| Agranulocytosis | 1 | haemorrhage | | 1 |
| Haemolytic anaemia | | Intestinal perforation | . 15 | 5 |
| Dependence | | Intestinal obstruction | | 2 |
| Debility | | Intestinal ulceration | | |
| Impotence | 1 | Salivary gland swelling | . 2 | |
| Somnolence | 1 | Gastro-intestinal haemorrange | | 3 |
| Headache | 2 | Constipation | 1 | |
| Tremor | 1 | Diarrhoea | 8 | |
| Paraesthesia | 1 | Nausea and vomiting | 6 | |
| Sleep disorder | 2 | Abdominal pain | 3 | |
| Giddiness | | Urticaria | 1 | |
| Vertigo | | Purpura | 1 | |
| Hypotension | | Exfoliative dermatitis | 1 | 1 |
| Thromobosis (peripheral | | Lupoid reaction | | 1 |
| artery) | . 1 | Photosensitivity | 1 | |
| Wascular disorders | | Psoriasis | 1 | |
| Arrhythmia | . 1 | Pruritus | . 1 | |
| Angina | | Other skin reactions | . 3 | |
| Chestpain | 1 | Shivering | | |
| Jaundice | | Pyrexia | . 1 | |
| Abnormal liver function tests | 2 | Overdose | . 1 | 1 |

Mersaly1 (68001)

Total reports June 1964-October 1971 21 (7 fatal) Reports not listed 7 (3 fatal)

| | Total | Deaths |
|--------------------|-------|--------|
| Gout | 1 | |
| Thrombocytopenia | 2 | 2 |
| Neuritis | 1 | |
| Cardiac arrest | 1 | 1 |
| Gingivitis | 2 | |
| Diarrhoea | 1 | |
| Skin reactions | 4 | 1 |
| Anaphylactic shock | 1 | |
| Rigor | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 49,000 |
|---------------|---------|-----|------|--------|
| | H | # | 1969 | 32,000 |
| El . | W | | 1970 | 25,000 |

Mercaptomerin (68005)

Total reports January 1969-October 1971 1
Reports not listed Nil

Total Deaths

Gastro-intestinal haemorrhage

Theobromine (68101)

'Hormofemin Compound', Riddospas', 'Seominal', 'Theogardenal', 'Theominal'

Total reports March 1965-October 1971 8 (1 fatal)
Reports not 11sted 2

| | Total | Deaths |
|--|--------|--------|
| Loss of control of diabetes Skin reactions | 1 5 | 1 |

| Prescriptions | (EC 10) | for 1968 | 136,000 |
|---------------|---------|----------|---------|
| H | Ħ | 1969 | 174,000 |
| N | Ħ | 1970 | 149.000 |

Hexyltheobromine (68102)

Cosaldon

| otal | reports | June | 1964-0 | ctobe | er | 1971 | 4 |
|------|---------|------|---------|-------|----|------|---|
| | | | Reports | | | | |

| | Total | Deaths |
|--------------------|-------|--------|
| Visual disturbance | 1 | |
| Skin reaction | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 14,000 |
|---------------|---------|-----|------|--------|
| | | H | 1969 | 12,000 |
| | | | 1970 | 13,000 |

Bufylline (68108)

'Nethaprin Dospan', 'Nethaprin Expectorant'

Total reports January 1965-October 1971 4 (1 fatal)
Reports not listed Nil

| | Total | Deaths |
|------------------|-------|--------|
| Increased libido | 1 | |
| Headache | 1 | |
| Sleep disorder | 1 | |
| Renal failure | 1 | 1 |

| Prescriptions | (EC 10) | for | 1968 | 58,000 |
|---------------|---------|-----|------|---------|
| H | Ħ | 11 | 1969 | 54,000 |
| H | Ħ | H | 1970 | 100,000 |

Chlorothiazide (68201)

'Lyovac Saluric', 'Saluric'

Notal reports May 1964-October 1971 52 (3 fatal)
Reports not listed 15

| | Total | Deaths |
|-------------------------------|-------|--------|
| Diabetes mellitus | 2 | 1 |
| Thrombocytopenia | 4 | |
| Leucopenia | 1 | |
| Agranulocytosis | 2 | 2 |
| Neutropenia | 1 | |
| Aplastic anaemia | 2 | |
| Depression | 1 | |
| Neuritis | 1 | |
| Generalised weakness | 2 | |
| Chestpain | 1 | |
| Jaundice | 3 | |
| Abnormal liver function tests | 5 | |
| Stomatitis | 1 | |
| Diarrhoea | 1 | |
| Nausea and vomiting | 2 | |
| Urticaria | 1 | |
| Angioneurotic oedema | 1 | |
| Purpura | 3 | |
| Exfoliative dermatitis | , | |
| Eczema | | |
| | | |
| Other skin reactions | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 286,000 |
|---------------|---------|-----|------|---------|
| H | M | 10 | 1969 | 354,000 |
| | W | * | 1970 | 330,000 |

Hydrochlorothiazide (68202)

'Direma', 'Esidrex', 'Hydromet', 'Hydrosaluric', 'Salupres', 'Serpasil-Esidrex'

Total reports May 1964-October 1971 130 (15 fatal) Reports not listed 46 (8 fatal)

| | Total Deaths | | Total | Deaths |
|--------------------------------|--------------|-------------------------------|-------|--------|
| Diabetes mellitus | 8 | Arrhythmia | 1 | |
| Hypokalaemia | 1 | Jaundice | 1 | |
| Hyponatremia | 1 | Abnormal liver function tests | 3 | |
| Thrombocytopenia | 6 3 | Intestinal perforations | 5 | 1 |
| Agranulocytosis | 2 1 | Intestinal ulceration | 1 | |
| Coagulation defect | 1 | Salivary gland swelling | 1 | |
| Depression | 2 | Gastro-intestinal haemorrhage | . 2 | 1 |
| Memory impairment | 1 | Constipation | 1 | |
| Neuropathy | 1 | Diarrhoea | 2 | |
| Dyskinesia | 1 | Nausea and vomiting | 2 | |
| Convulsion | 1 | Abdominal pain | 1 | |
| Syncope | 3 | Renal failure | 1 | |
| Somnolence | 2 | Urticaria | 2 | |
| Paraesthesia | 1 | Purpura | 3 | |
| Visual disturbance | 1 | Photosensitivity | 6 | 1 |
| Mydriasis | 1 | Necrosis of skin | | - |
| Tinnitus | 1 | (not from injection) | 1 | |
| Hypotension | 1 | Psoriasis | 1 | |
| Hypertension | 1 | Lichenoid | `1 | |
| Thrombosis (peripheral artery) | 1 | Other skin reactions | 6 | |
| Palpitations | 1 | Pyrexia | 2 | |
| Tachycardia | 1 | Muscle pain | 2 | |

| Prescriptions | (EC 10) | for | 1968 | 348,000 |
|---------------|---------|-----|------|-----------|
| 11 | 11 | 11 | 1969 | 339,000 |
| 12 | 11 | 11 | 1970 | 1,045,000 |

Methyclothiazide (68204)

'Enduron!, 'Enduronyl'

Total reports July 1964-October 1971 6 Reports not listed Nil

| | Total | Deaths |
|----------------|-------|--------|
| Neuritis | 1 | |
| Gingivitis | 1 | |
| Skin reactions | 4 | |

| Prescriptions | (EC 10) | for | 1968 | 80,000 |
|---------------|---------|-----|------|--------|
| | | * | 1969 | 56,000 |
| N N | ¥ | | 1970 | 47,000 |

Polythiazide (68206)

'Nephril'

Total reports March 1964-October 1971 46 (3 fatal) Reports not listed 11 (1 fatal)

| | Total | Deaths |
|-------------------------------|-------|--------|
| Diabetes mellitus | 2 | |
| Hypokalaemia | 3 | |
| Thrombocytopenia | 1 | |
| Agranulocytosis | 1 | 1 |
| Pancytopenia | 1 | |
| Aplastic anaemia | 1 . | 1 |
| Depression | 1 | |
| Debility | 1 | |
| Impotence | 1 | |
| Syncope | 2 | |
| Somnolence | 2 | |
| Visual disturbance | 1 | |
| Hypotension | 1 | |
| Hypertension | 1 | |
| Palpitations | 1 | |
| Angina | 1 | |
| Coronary occulsion | 1 | |
| Cough | 1 | |
| Abnormal liver function tests | 6 | |
| Nausea and vomiting | 1 | |
| Abdominal pain | 2 | |
| Photosensitivity | 1 | |
| Joint symptoms N.O.S | 1 | |
| Muscle pain | 1 | |

| Prescriptions | EC 10) | for | 1968 | 323,000 |
|---------------|--------|-----|------|---------|
| # | Ħ | W | 1969 | 339,000 |
| H | 10 | Н | 1970 | 375,000 |

Benzthiazide (68208)

'Decaserpyl Plus', 'Dytide'

Total reports October 1964-October 1971 23 Reports not listed Nil

| | Total | Deaths |
|-----------------------------|-------|--------|
| Breast hypertrophy (female) | 1 | |
| Diabetes mellitus | 1 | |
| Oedema | 2 | |
| Leucopenia | 1 | |
| Depression | 3 | |
| Neurosis | 1 | |
| Parkinsonism | 1 | |
| Headache | 1 | |
| Giddiness | 1 | |
| Tinnitus | 1 | |
| Bronchospasm | 1 | |
| Rhinitis | 1 | |
| Glossitis | 1 | |
| Diarrhoea | 2 | |
| Abdominal pain | 1 | |
| Skin reactions | 2 | |
| Muscle pain | 2 | |

| Prescriptions | (EC 10) | for 1968 | 137,000 |
|---------------|---------|----------|---------|
| W | 19 | 1969 | 127,000 |
| | W | * 1970 | 134,000 |

Cyclopenthiazide (68210)

'Navidrex', 'Ismelin-Navidrex'

Total reports June 1964-October 1971 85 (5 fatal)
Reports not listed 37 (2 fatal)

| | Total D | eaths | | Total Deaths |
|--------------------------------|---------|-------|-------------------------------|--------------|
| Gynaecomastia (male) | 1 | | Gastro-intestinal haemorrhage | 1 |
| Diabetes mellitus | | | Diarrhoea | 1 |
| Weight loss | _ | | Nausea and vomiting | 2 |
| Hypokalaemia | | | Abdominal pain | |
| Thrombocytopenia | | 1 | Haematuria | |
| Haemolytic anaemia | | | Urticaria | |
| Confusional state | | | Purpura | - |
| | , | | Exfoliative dermatitis | _ |
| Encephalitis | | | | |
| Neuropathy | , - | | Lupoid reaction | |
| Involuntary spasm of | | | Photosensitivity | |
| facial muscles | _ | | Eczema | |
| Somnolence | _ | | Hair colour change | |
| Headache | | | Congenital abnormality | |
| Generalised weakness | | | Shivering | 1 |
| Paraesthesia | , 3 | | Pyrexia | 1 |
| Vertigo | 1 | | Muscle pain | . 1 |
| Bradycard | | | Reaction after | |
| Chestpain | | • | consuming mushrooms | . 1 |
| Gastric ulcer with haemorrhage | _ | 1 | | |

| Prescriptions | (EC 10) | for | 1968 | 778,000 |
|---------------|---------|-----|------|-----------|
| | 11 | 12 | 1969 | 1,056,000 |
| 11 | 11 | 11 | 1970 | 1.275.000 |

Bendrofluazide (68220)

'Abicol', 'Aprinox', 'Berkozide', 'Centyl'
'Neo-Naclex', 'Tensanyl', 'Tenavoid'

 Total reports June 1964-October 1971
 126 (8 fatal)

 Reports not listed
 28 (4 fatal)

| | Total | Deaths | | Total | Deaths |
|----------------------|-------|--------|-------------------------------|-------|--------|
| Gynaecomastia (male) | 2 | | Tinnitus | 1 | |
| Diabetes mellitus | 6 | | Hypotension | 3 | |
| Gout | • | | Chestpain | 1 | |
| Oedema | 1 | 1 | Haemoptysis | . 1 | |
| Acidosis | 1 | 1 | Jaundice | 2 | |
| Hypokalaemia | 1 | | Gingivitis | 1 | |
| Tetany | | | Dysphagia | 1 | |
| Thrombocytopenia | | 2 | Gastro-intestinal haemorrhage | 1 | |
| Pancytopenia | i | | Constipation | 1 | |
| Haemolytic anaemia | 3 | | Nausea and vomiting | 6 | |
| Depression | - | | Abdominal pain | 2 | |
| Dependence | | | Urticaria | 5 | |
| Debility | | | Purpura | 1 | |
| Impotence | | | Morbilliform rash | 3 | |
| Neuritis | | | Erythema multiforme | 1 | |
| Convulsion | | | Photosensitivity | 2 | |
| Somnolence | 2 | | Eczema | 1 | |
| Generalised weakness | 1 | | Lichenoid | 1 | |
| Gait disorder | 1 | | Lichen planus | 1 | |
| Tremor | 1 | | Pruritus | 1 | |
| Sensory disturbance | | | Other skin reactions | 12 | |
| Sleep disorder | 1 | | Intrauterine death | 1 | |
| Giddiness | | | Muscle pain | 2 | |

| Prescriptions | (EC 10) | for | 1968 | 1,146,000 |
|---------------|---------|-----|------|-----------|
| H | ti | 11 | 1969 | 1,285,000 |
| 17 | 11 | 11 | 1970 | 1,593,000 |

Hydroflumethiazide (68222)

'Aldactide', 'Hydrenox', 'Naclex', 'Rautrax'

Total reports October 1964-October 1971 23 (2 fatal) Reports not listed 6

| | Total | Deaths |
|---------------------|-------|--------|
| Hypoglycaemia | 1 | 1 |
| Thrombocytopenia | 1 | |
| Pancytopenia | 2 | 1 |
| Haemolytic anaemia | 1 | |
| Depression | 1 | |
| Mental disorder | 1 | |
| Impotence | 1 | |
| Nausea and vomiting | 1 | |
| Abdominal pail | 1 1 | |
| Urethritis | 1 | |
| Skin reactions | 4 | |
| Muscle pain | 1 | |
| Sepsis | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 293,000 |
|---------------|---------|-----|------|---------|
| | Ħ | 11 | 1969 | 312,000 |
| | М | | 1970 | 282,000 |

Chlorthalidone (68230)

'Hygroten'

otal reports March 1964-October 1971 40 (6 fatal)
Reports not listed 12 (1 fatal)

| | Total | Deaths |
|---------------------|-------|--------|
| | | |
| Hypothyroidism , | 1 | |
| Diabetes mellitus | 3 | |
| Hypokalaemia | 1 | 1 |
| Thrombocytopenia | 2 | 1 |
| Agranulocytosis | _ | • |
| Neutropenia | | 4 . |
| | | |
| Hallucinations | 1 | |
| Sommolence | 1 | |
| Headache | 1 | |
| Giddiness | 1 | |
| Dipkopia | 1 | |
| Palpitations | | |
| Arrhythmia | | |
| Jaundice | | 1 |
| | 1 | • |
| Diarrhoea | 1 | |
| Nausea and vomiting | | |
| Abdominal pain | 1 | |
| Renal failure | 1 | 1 |
| Uraemia | 1 | |
| Vaginitis | 1 | |
| Skin reactions | 5 | |
| | | |

| Prescriptions | (EC 10) | for | 1968 | 372,000 |
|---------------|---------|-----|------|---------|
| | * | * | 1969 | 375,000 |
| | | | 1970 | 312,000 |

Clorexolone (68233)

'Ne frolan'

Total reports February 1965-October 1971 7 Reports not listed Nil

| | Total | Deaths |
|-------------------------------|-------|--------|
| Diabetes mellitus | 1 | |
| Debility | 1 | |
| Impotence | 1 | |
| Giddiness | 1 | |
| Visual disturbance | 1 | |
| Superficial venous thrombosis | 1 | |
| Skin reaction | 1, | |

| Prescriptions | (EC 10) | for | 1968 | 31,000 |
|---------------|---------|-----|------|--------|
| N | N | 10 | 1969 | 25,000 |
| H | W | 18 | 1970 | 44,000 |

Acetazolamide (68260)

'Acetazide', 'Diamox'

Total reports April 1964-October 1971 20 (2 fatal) Reports not listed 3

| | Total | Deaths |
|--------------------------|-------|--------|
| Osteoporosis | 1 | |
| Aplastic anaemia | 1 | 1 |
| Neuropathy | 1 | |
| Neuritis | 1 | |
| Paraesthesia | 1 | |
| Sensory disturbance | 1 | |
| Jaundice | 1 | 1 |
| Renal calculus | 2 | |
| Haematuria | 1 | |
| Skin reactions | 3 | |
| Congenital abnormalities | 4 | |

| Prescriptions | (EC 10) | for | 1968 | 75,000 |
|---------------|---------|-----|------|--------|
| 11 | Ħ | 11 | 1969 | 88,000 |
| 16 | 11 | 11 | 1970 | 80,000 |

Dichlorphenamide (68265)

'Daranide', 'Oratrol'

Total reports August 1964-October 1971 10 Reports not listed 1

| | Total | Deaths |
|--------------------|-------|--------|
| Paraesthesia | 3 | |
| Visual disturbance | 1 | |
| Diarrhoea | 3 | |
| Drymouth | 1 | |
| Skin reaction | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 13,000 |
|---------------|---------|-----|------|--------|
| 11 | н | 11 | 1969 | 9,000 |
| 11 | н | 11 | 1970 | 13,000 |

Frusemide (68270)

'Lasix'

Total reports January 1965-October 1971 398 (48 fatal) Reports not listed 67 (15 fatal)

| | Total | Deaths | | Total | Deaths |
|-----------------------------|-------|--------|--|---------|--------|
| Gynaecomastia (male) | 5 | | Heart failure | 2 | 2 |
| Pancreatic disorder | 1 | 1 | Dyspnoea | 2 | _ |
| Diabetes mellitus | 9 | | Apnoea | 1 | 1 |
| Hyperglycaemia | 3 | | Rhinitis | 1 | * |
| Loss of control of diabetes | ' 3 | | Jaundice | 18 | 7 |
| Gout | 15 | | Abnormal liver function | 20 | |
| Oedema | 1, | | tests | 1 | |
| Hypokalaemia | 5 | 2 | .Duodenal ulcer with | | |
| Tetany | 1 | | haemorrhage | 1 | 1 |
| Eosinophilia | 1 | | Intestinal perforation | ī | 1 |
| Thrombocytopenia | 15 | 4 | Intestinal obstruction | 2 | |
| Leucopenia | 2 | | Stomatitis | 1 | |
| Agranulocytosis | 12 | 5 | Salivary gland swelling | 2 | |
| Neutropenia | 1 | 1 | Glossitis | 1 | |
| Haemolytic anaemia | 3 | 2 | Dysphagia | 1 | • |
| Aplastic anaemia | 2 | 1 | Gastro-intestinal | * | |
| Macrocytic anaemia | 1 | | haemorrhage | 2 | |
| Coagulation defect | 1 | 1 | | | |
| Mania | 1 | | Ileus | 1 | |
| Depression | 1 | | Constipation | 2 | |
| Dependence | 1 | | Diarrhoea | 4 | |
| Confusional state | 1 | | Nausea and vomiting | 12 | |
| Hallucinations | 2 | | Abdominal pain | 5 | |
| Mental disorder | | | Renal failure | 1 | |
| Increased libido | | | Nephrotic syndrome | 1 | |
| Neuropathy | | | Renal colic | 1 | |
| | - | | Uraemia | 2 | |
| Neuritis | _ | | Haematuria | 1 | |
| Syncope | | 1 | Glycosuria | 1 | |
| Somnolence | | | Urticaria | 12 | |
| Headache | | | Purpura | 20 | 1 |
| Tremor | - | | Morbilliform rash | 2 | |
| Paraesthesia | _ | | Scarlatiniform rash | 1 | |
| Sleep disorder | _ | | Erythema multiforme | 4 | |
| | | | Erythema nodosum Exfoliative dermatitis | 1 | |
| Giddiness | 2 | | Lupoid reaction | 5 | |
| Visual disturbance | 6 | | | 1 | |
| Colour blindness | 1 | | Photosensitivity | 3 | |
| Nerve deafness | 7 | | Eczema | 3 | |
| Tinnitus | 1 | | Necrosis of skin (not | , | |
| Vertigo | 5 | | from injection) | 1 | |
| Hypotension | 5 | 1 | Nail changes | 1 | |
| Shock (not anaphylactic). | 2 | | Lichenoid | 1 | |
| Thrombosis inferior | | | Lichen planus | 2 | |
| vena cava | 1 | | Pruritus | 3 | |
| Vasoconstriction | 1 | | Other skin reactions | ر 45 | |
| Vascular disorders | 1 | | Anaphylaxis | 2 | |
| Vasculitis | 2 | | Pyrexia | 2 | |
| Palpitations | 1 | | Periarteritis nodosa | 1 | |
| Bradycard | 1 | | Muscle pain | 1 | |
| Cardiac arrest | 1 | | | - | |
| Angina | 1 | | | | |

| Prescriptions | (EC 10) | for | 1968 | 2,518,000 |
|---------------|---------|-----|------|-----------|
| | | | | 2,686,000 |
| 11 | 39 | 11 | 1970 | 2,939,000 |

Clopamide (68301)

'Brinaldix'

Total reports May 1968-October 1971 5 Reports not listed Nil

| | Total, | Deaths |
|-----------------------------|--------|--------|
| Loss of control of diabetes | 1 | |
| Thrombocytopenia | 1 | |
| Tremor | 1 | |
| Skin reaction | 2 | |

Spironolactone (68803)

'Aldactide', 'Aldactone-A'

otal reports February 1965-October 1971 44 (4 fatal)
Reports not listed 5 (1 fatal)

| | Total | Deaths |
|------------------------|-------|--------|
| Amenorrhoea | 1 | |
| Gynaecomastia (male) | 11 | |
| Gout | 1 | |
| Hypokalaemia | 1 | |
| Thrombocytopenia | 1 | |
| Agranulocytosis | 2 | 1 |
| Psychosis | 1 | |
| Neuropathy | 1 | |
| Coma | 1 | |
| Flushing | 1 | |
| Tremor | 1 | |
| Visual disturbance | 1 | |
| Tinnitus | 1 | |
| Vasculitis | 1 | |
| Jaundice | 2 | 1 |
| Nausea and vomiting | 1 | |
| Urticaria | 1 | |
| Angioneurotic oedema | 1 | |
| Exfoliative dermatitis | ī | |
| Hyperkeratosis | 2 | |
| Vitiligo | 1 | 1 |
| Pruritus | 1 | _ |
| Other skin reactions | 3 | |
| | | |
| Muscle pain | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 113,000 |
|---------------|---------|-----|------|---------|
| 19 | 11 | 15 | 1969 | 142,000 |
| 11 | 19 | 11 | 1970 | 193.000 |

Metyrapone (68805)

'Metopirone'

Total recorts March 1964-October 1971 2
Reports not listed Nil

| | Total Deaths |
|------------|--|
| enorrhagia | 1 |
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Amiloride (68810)

'Midamor', 'Moduretic'

Total reports April - October 1971 15 Reports not listed

| 098 | Festi | • | Total | No Deaths |
|-------|------------|-----------------|----------|-----------|
| Hypor | natremia . | | er i | |
| | opathy | | | |
| | ope | | 2 | |
| | olence | | 1 | |
| Mydr: | iasis | | 1 | |
| Palp | itations . | | 1 | |
| Cons | tipation . | | 1 | |
| Diar | rhoea | • • • • • • • • | 1 | |
| Rena | l failure | | 1 | |
| | reactions | | 2 | |
| Pyre | xia | | 1 | |
| | le pain | | 2 | |

Aminometradine (68901)

'Entramin'

Total reports February 1965-October 1971 1
Reports not listed Nil

Triamterene (68905)

'Dytac', 'Dytide'

Total reports October 1964-October 1971 18 Reports not 11sted 2

| | Total | Deaths |
|-----------------------------|-------|--------|
| Breast hypertrophy (female) | 1 | |
| Diabetes mellitus | 1 | |
| Leucopenia | 1 | |
| Neuritis | 1 | |
| Headache | 1 | |
| Migraine | 1 | |
| Giddiness | 1 | |
| Vasculitis | 1 | |
| Rhinitis | 1 | |
| Glossitis | 1 | |
| Diarrhoea | 1 | |
| Abdominal pain | 1 | |
| Purpura | 1 | |
| Exfoliative dermatitis | 1 | |
| Other skin reaction | 1 | |
| Muscle pain | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 89,000 |
|---------------|---------|-----|------|--------|
| | 10 | 11 | 1969 | 76,000 |
| | | | 1970 | 64,000 |

Ethacrynic Acid (68910)

'Edecrin'

Total reports June 1964-October 1971 25 (5 fatal)
Reports not listed 1

| | Total | Deaths |
|----------------------|-------|--------|
| Gynaecomastia (male) | 1 | |
| Thrombocytopenia | 1 | |
| Agranulocytosis | 3 | 3 |
| Neuritis | 1 | |
| Somnolence | 1 | |
| Visual disturbance | 1 | |
| Nerve deafness | 1 | |
| Coronary occlusion | 1 | 1 |
| Heart failure | 1 | 1 |
| Jaundice | 1 | |
| Diarrhoea | 4 | |
| Nausea and vomiting | 2 | |
| Anorexia | 1 | |
| Skin reactions | 5 | |

| Prescriptions | (EC 10) | for | 1968 | 35,000 |
|---------------|---------|-----|------|--------|
| tt tt | N. | 11 | 1969 | 35,000 |
| H | M | * | 1970 | 25,000 |

Pancreatin (69005)

Combizym', Enzypan', Panar', Pancrex'

Total reports January 1965-October 1971 4
Reports not listed 1

Total Deaths

Gynaecomastia (male) 3

| Prescriptions | (EC 10) | for | 1968 | 26,000 |
|---------------|---------|-----|------|--------|
| 19 | | | 1969 | |
| 11 | 11 | н | 1970 | |

Trypsin (69009)

Chymoral, *Chymocyclar*, *Ototrips*, *Trypure Novo*

Total reports January 1966-October 1971 9 Reports not listed 1

| | Total | Deaths |
|--------------------|-------|--------|
| Coagulation defect | 2 | |
| Depression | 2 | |
| Skin reactions | 3 | |

| Prescriptions | (EC 10) | for | 1968 | 89,000 |
|---------------|---------|-----|------|--------|
| 11 | 11 | 11 | 1969 | 73,000 |
| Н | 11 | Н | 1970 | 76,000 |

Chymotrypsin (69010)

'Avazyme', 'Chymoral', 'Chymar', 'Chymocyclar', 'Lomudase'

Total reports November 1965-October 1971 12
Reports not listed 2

| | Total | Deaths |
|---------------------|-------|--------|
| Coagulation defect | 2 | |
| Depression | 1 | |
| Nausea and vomiting | 2 | |
| Skin reactions | 3 | |
| Anaphylactic shock | 1 | |
| Anaphylaxis | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 89,000 |
|---------------|---------|-----|------|--------|
| н | 11 | 11 | 1969 | 73,000 |
| 11 | п | 11 | 1970 | 77,000 |

Co balt Chloride (69101)

| Total reports | June 1968-October 1971 | 1 |
|---------------|------------------------|---|
| | Reports not listed | |

Total Deaths
Neuritis 1

Methylcysteine (69151)

'Aedrile'

Total reports August 1969-October 1971 1
Reports not listed NIL

| Prescriptions | (EC 10) | for | 1968 | 2,000 |
|---------------|---------|-----|------|-------|
| 11 | H | ff | 1969 | 2,000 |
| 11 | П | н | 1970 | 1,000 |

Probenecid (69201)

Benemid, *Colbenemid*, *Penbenemid*

Total reports November 1964-October 1971 43 (8 fatal) Reports not listed 8 (1 fatal)

| | Total | Deaths |
|------------------------|-------|--------|
| Thrombocytopenia | 2 | 1 |
| Leucopenia | 1 | |
| Agranulocytosis | 2 | 1 |
| Haemolytic anaemia | 1 | 1 |
| Leukaemia | 2 | 2 |
| Confusional state | 1 | |
| Reduced libido | 2 | |
| Neuropathy | 2 | |
| Convulsion | 1 | 1 |
| Headache | 1 | |
| Abnormal movements | 1 | |
| Visual disturbance | 1 | |
| Cardiac arrest | 1 | 1 |
| Rhinitis | 1 | |
| Nausea and vomiting | 1 | |
| Nephrotic syndrome | 1 | |
| Angioneurotic oedema | 2 | |
| Purpura | 2 | |
| Morbilliform rash | 2 | |
| Erythema multiforme | 1 | |
| Exfoliative dermatitis | 1 | |
| Pruritus | 1 | |
| Other skin reaction | 1 | |
| Congenital abnormality | 1 | |
| Anaphylactic shock | 1 | |
| Anaphylaxis | 1 | |
| Rigor | 1 | |
| | | |

| Prescriptions | (EC 10) | for | 1968 | 77.000 |
|---------------|---------|-----|------|--------|
| II | 11 | 11 | 1969 | 68,000 |
| Ħ | 11 | 11 | 1970 | 67.000 |

Ethebenecid (69204)

Urelim

Total reports April 1968-October 1971 2

Reports not listed NIL

Total Deaths

Skin reaction 2

| Prescriptions | (EC 10) | for | 1968 | 4,000 |
|---------------|---------|-----|------|-------|
| Ħ | H | n | 1969 | 3,000 |
| 11 | Ħ | 11 | 1970 | 1,000 |

Sulphinpyrazone (69205)

Anturan

Total reports November 1964-October 1971 10
Reports not listed 2

| | Total | Deaths |
|------------------|-------|--------|
| Thrombocytopenia | 3 | |
| Agranulocytosis | 1 | |
| Impotence | 1 | |
| Diarrhoea | 1 | |
| Renal calculus | 2 | |

| Prescriptions | (EC 10) | for | 1968 | 18,000 |
|---------------|---------|-----|------|--------|
| H | н | п | 1969 | 22,000 |
| 11 | n | 11 | 1970 | 13,000 |

Allopurinol (69207)

'Zyloric'

Total reports May 1966-October 1971 82 (6 fatal) Reports not listed 12

| | Total | Deaths |
|-------------------------------|-------|--------|
| Gynaecomastia (male) | 1 | |
| Infertility (male) | 1 | |
| Diabetcs mellitus | 1 | |
| Oedema | 1 | |
| Thrombocytopenia | 2 | |
| Leucopenia | 1 | |
| Haemolytic anaemia | 1 | 1 |
| Leukaemia | 3 | 2 |
| Impotence | 1 | |
| Lymphadenopathy | 1 | |
| Neuropathy | 2 | |
| Abnormal movements | 1 | |
| Cataract | 3 | |
| Visual disturbance | 1 | |
| Tinnitus | 1 | |
| Bradicardia | 1 | |
| Coronary occlusion | 1 | 1 |
| Asthma | 1 | |
| Epistaxis | 1 | |
| Jaundice | 2 | 1 |
| Abnormal liver function tests | 1 | |
| Stomatitis | 1 | |
| Salivary gland swelling | 1 | |
| Gastro-intestinal | | |
| haemorrhage | 2 | |
| Diarrhoea | 2 | |
| Nausea and vomiting | 2 | |
| Abdominal pain | 3 | |
| Anorexia | 1 | |
| Urticaria | 2 | |
| Purpura; | 2 | |
| Morbilliform rash | 2 | |
| Stevens Johnson Syndrome | 2 | |
| Exfoliative dermatitis | 4 | |
| Other skin reactions | 16 | |
| Reaction after alcohol | 1 | |
| Carcinoma | 1 | 1 |
| | | |

| Prescriptions | (EC 10) | for | 1968 | 41,000 |
|---------------|---------|-----|------|--------|
| н | 18 | | 1969 | 58,000 |
| ti | 11 | 11 | 1970 | 88,000 |

Desferrioxamine Mesylate (69301)

'Desferal'

Total reports May 1965-October 1971 3 Reports not listed Nil

| | Total | Deaths |
|----------|-------|--------|
| Cataract | 2 | |
| Scotoma | 1 | |

D-Penicillamine (69305)

'Cuprimine', 'Distamine'

Total reports February 1966-October 1971 7 (1 fatal) Reports not listed Nil

| | Total | Deaths |
|--------------------|-------|--------|
| Agranulocytosis | 2 | |
| Aplastic anaemia | 1 | 1 |
| Nephrotic syndrome | 1 | |
| Skin reaction | 3 | |

Methionine (69903)

'G.500'

Total reports August 1965-October 1971 3
Reports not listed 1

Total Deaths
Skin reactions 2

Intralipid (69907)

'Intralipid Vitrum'

Total reports November 1969-October 1971 1
Reports not listed Nil

L-Dopa (69909)

'Brocadopa', 'Larodopa', 'Levopa'

Total reports September 1969-October 1971 43 (5 fatal) Reports not listed 8 (2 fatal)

| | Total | Deaths |
|-----------------------------|-------|--------|
| Discolouration of urine | 1 | |
| Psychosis | 2 | |
| Hallucinations | 2 | |
| Mental disorder | 1 | 1 |
| Debility | 1 | |
| Paralysis | 1 | |
| Convulsion | 1 | |
| Coma | 1 | |
| Cerebrovascular disorders . | 1 | |
| Flushing | 1 | |
| Generalised weakness | 1 | |
| Abnormal movements | 1 | |
| Cyanosis | 1 | |
| Cardiac arrest | 1 | 1 |
| Coronary occlusion | 3 | 1 |
| Jaundice | 1 | |
| Glossitis | 1 | |
| Gastro-intestinal | | |
| haemorrhage | 1 | |
| Constipation | 1 | |
| Nausea and vomiting | 4 | |
| Urticaria | 1 | |
| Purpura | 1 | |
| Dryskin | 1 | |
| Alopacia | 2 | |
| Seborrhoea | 1 | |
| Other skin reactions | 2 | |

Saccharin (69910)

| Total | reports | March | 1967-0 | ctobe | r 1971 | 3 |
|-------|---------|-------|---------|-------|--------|---|
| | | | Reports | | | |

Total Deaths

Gait disorder 1

Benzylpenicillin (Penicillin G) (70002)

'Cathopen', 'Crystamycin', 'Crystapen', 'Distaquaine Fortified', 'Distavone'
'Eskacillin', 'Falapen', 'Hyasorb', 'Penbenemid', 'Penidural', 'Purapen'
'Seclomycin', 'Seclopen', Solupen', 'Soluvone', 'Triplopen'

Total reports June 1964-October 1971 77 (5 fatal)
Reports not listed 10 (1 fatal)

| | Total | Deaths |
|--------------------------|-------|--------|
| Agranulocytosis | 2 | |
| Haemolytic anaemia | 1 | |
| Hallucinations | 1 | |
| Syncope | 2 | |
| Conjunctivitis | 1 | |
| Diplopia | 1 | |
| Hypotension | 1 | |
| Shock (non anaphylactic) | 1 | |
| Jaundice | 1 | |
| Diarrhoea | 1 | |
| Nausea and vomiting | 1 | |
| Abdominal pain | 1 | |
| Urticaria | 10 | |
| Morbilliform rash | | |
| Other skin reactions | | |
| Anaphylactic shock | | 3 |
| Anaphylaxis | 5 | 1 |
| Atrophy following | | |
| subcutaneous injection | 1 | |
| Fibrosis following | | |
| intra-muscular injection | 5 | |
| Oedema following | | |
| intra-muscular injection | 1 | |
| Pain following | | |
| intra-muscular injection | 1 | |

Procaine Penicillin (70003)

'Avloprocil', 'Distaquaine', 'Distavone', 'Duracillin', 'Lenticillin' 'Penidural', 'Prostabillin', 'Seclopen', 'Tampovagan PSS', 'Triplopen'

Total reports May 1964-October 1971 35 (4 fatal) Reports not listed 3 (1 fatal)

| | Total | Deaths |
|--------------------------|-------|--------|
| Mental disorder | 2 | |
| Syncope | 2 | |
| Tremor | 1 | |
| Hypotension | 1 | |
| Palpitations | 1 | |
| Jaundice | 1 | |
| Nausea and vomiting | 1 | |
| Urticaria | 4 | |
| Angioneurotic oedema | 1 | |
| Morbilliform rash | 1 | |
| Other skin reactions | 5 | |
| Anaphylactic shock | 6 | 2 |
| Anaphylaxis | 3 | 1 |
| Atrophy following | | |
| subcutaneous injection | 1 | |
| Oedema following | | |
| intra-muscular injection | 1 | |
| Pain following | | |
| intra-muscular injection | 2 | |

| Prescriptions | (EC 10) | for 1968 | 83,000 |
|---------------|---------|----------|--------|
| N: | | | |
| B | 11 | " 1970 | 71,000 |

Benethamine Penicillin (70005)

'Triplopen'

Total reports July 1964-October 1971 22 (3 fatal) Reports not listed 2 (1 fatal)

| | Total | Deaths |
|---|--------|--------|
| Syncope | 1 | |
| Hypotension | 1 | |
| Urticaria | 4 3 | |
| Anaphylactic shock | 5 2 | 1 1 |
| Atrophy following subcutaneous injection | 1 | |
| Oedema following intra-muscular injection | 1 | |
| Pain following intra-muscular injection | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 41,000 |
|---------------|---------|-----|------|--------|
| tt | 11 | | 1969 | |
| 11 | Ħ | tt | 1970 | 35,000 |

Benzathine Penicillin (70006)

'Dibencil', Penidural'

Total reports February 1966-October 1971 7 Reports not listed 2

| | Total | Deaths |
|-------------|-------|--------|
| Syncope | 1 2 2 | |
| Anaphylaxis | 2 | |

| Prescriptions | (EC 10) | for | 1968 | 1,311,000 |
|---------------|---------|-----|------|-----------|
| n | 11 | 11 | 1969 | 1,049,000 |
| 11 | 11 | 11 | 1970 | 943,000 |

Propicillin (70007)

'Brocillin', 'Ultrapen'

Total reports December 1964-October 1971 13 Reports not listed 1

| | Total | Deaths |
|--|-------------|--------|
| Eosinophilia Oesophagitis Skin reactions | 1 8 3 | |

| Prescriptions | (EC 10) | for | 1968 | 323,000 |
|---------------|---------|-----|------|---------|
| II | 11 | tt | 1969 | 220,000 |
| tt. | ti | 13 | 1970 | 128,000 |

Phenethicillin (70009)

'Broxil'

Total reports June 1964-October 1971 26 (1 fatal) Reports not listed 5 (1 fatal)

| | Total | Deaths |
|-------------------------|-------|--------|
| Thrombocytopenia | 1 | |
| Depression | 1 | |
| Convulsion | 1 | |
| Syncope | 1 | |
| Sleep disorder | 1 | |
| Dyspnoea | 1 | |
| Jaundice | 1 | |
| Discolouration of teeth | 2 | |
| Nausea and vomiting | 2 | |
| Urticaria | 1 | |
| Purpura | 1 | |
| Morbilliform rash | 1 | |
| Moniliasis | 1 | |
| Other skin reactions | 5 | |
| Arthralgia | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 1,200,000 |
|---------------|---------|-----|------|-----------|
| 11 | Ħ | | 1969 | |
| Ħ | 11 | 11 | 1970 | 1,074,000 |

Penamecillin (70010)

'Havapen!

Total reports February 1967-October 1971 3 Reports not listed Nil

| | Total | Deaths |
|----------------|-------------|--------|
| Abdominal pain | 1 1 1 | |

| Prescriptions | (EC 10) | for | 1968 | 325,000 |
|---------------|---------|-----|------|---------|
| H | 11 | 11 | 1969 | 186,000 |
| 11 | 17 | n | 1970 | 161,000 |

Phenoxymethyl Penicillin (Penicillin V)(70011)

'Co-caps Penicillin V-K', 'Compcillin V-K', 'CrystapenV', 'Distaquaine V', 'Distaquaine V-K' 'Econocil V-K', 'Econopen V', 'Icipen', 'Orapen V-K', 'Penavlon', 'Penicals', 'Penitriad' 'Stabillin V-K', 'V-Cil-K', 'V-Cil-K Sulpha', 'Tonsillin'

Total reports May 1964-October 1971 86 (2 fatal) Reports not listed 12 (1 fatal)

| | Total | Deaths |
|---|--|--------|
| Aplastic anaemia Depression Debility Somnolence Paraesthesia Sensory disturbance Giddiness Diplopia Hypotension Shock (non anaphylactic) Superficial venous thrombosis Proctitis Stomatitis Diarrhoea Nausea and vomiting | 1 1 1 4 1 1 1 1 1 1 1 1 1 1 1 1 | 1 |
| Urticaria | 18 1 3 1 1 20 2 6 | |

| Prescriptions | (EC 10) | for | 1968 | 8,274,000 |
|---------------|---------|------|------|-----------|
| 11 | tī | 11 | 1969 | 7,872,000 |
| 11 | 11 | - 11 | 1970 | 7,670,000 |

Cloxacillin (70013)

'Ampiclox', 'Orbenin'

Total reports June 1964-October 1971 37 (5 fatal) Reports not listed 10 (1 fatal)

| | Total | Deaths |
|----------------------|-------|--------|
| Thrombocytopenia | 2 | 1 |
| Leucopenia | 1 | |
| Agranulocytosis | 1 | |
| Neutropenia | 1 | |
| Pancytopenia | 1 | |
| Encephalitis | 2 | 1 |
| Oculogyric crisis | 1 | |
| Convulsion | 1 | 1 |
| Visual disturbance | 1 | |
| Gangrene | 1 | |
| Jaundice | 2 | |
| Stomatitis | 1 | |
| Diarrhoea | 1 | |
| Nausea and vomiting | 1 | |
| Uraemia | 1 | |
| Haematuria | 1 | |
| Purpura | 2 | |
| Morbilliform rash | 2 | 1 |
| Eczema | 1 | |
| Other skin reactions | 3 | |
| | | |

| Prescriptions | (EC 10) | for | 1968 | 54,000 |
|---------------|---------|-----|------|--------|
| II | Ħ | 17 | 1969 | 58,000 |
| H | II | 11 | 1970 | 81,000 |

Ampicillin (70015)

'Ampliclox', 'Penbritin', 'Penbritin KS'

Total reports May 1964-October 1971 783 (33 fatal) Reports not listed 91 (20 fatal)

| | Total D | Deaths | | Tota | al Deaths |
|-------------------------|---------|--------|-----------------------------|----------------|-----------|
| Oedema | 2 | | Discolouration of teeth | 2 | |
| Tetany | 1 | | Gingivitis | 1 | |
| Thrombocytopenia | 10 | | Stomatitis | 4 | |
| Leucopenia | 2 | 1 | Glossitis | 3 | |
| Agranulocytosis | 5 | 2 | Gastro-intestinal | | |
| Neutropenia | 1 | _ | haemorrhage | 2 | |
| Pancytopenia | ī | | Diarrhoea | 19 | |
| Haemolytic anaemia | 2 | | Nausea and vomiting | 4 | |
| Aplastic anaemia | 3 | 2 | Abdeminal pain | 1 | |
| Hypoplastic anaemia | í | _ | Renal failure | 1 | 1 |
| Depression | ī | | Nephrotic syndrome | 1 | |
| Confusional state | 3 | | Albuminuria | 1 | |
| Hallucinations | 3 | | Haematuria | 1 | |
| Mental disorder | 1 | | Vaginitis | 1 | |
| Encephalitis | 1 | | Urticaria | 99 | |
| Convulsion | 1 | 1 | Angioneurotic oedema | 4 | |
| Syncope | 2 | | Purpura | 13 | 2 |
| Somnolence | 2 | | Morbilliform rash | 65 | |
| Headache | 2 | | Scarlatiniform rash | 1 | |
| Hyperpyrexia | 2 | 1 | Bullous eruption | 1 | |
| Flushing | 1 | | Erythema multiforme | 11 | |
| Paraesthesia | 2 | | Stevens Johnson Syndrome | 2 | |
| Abnormal movements | 1 | | Exfoliative dermatitis | 7 | |
| Visual disturbance | 1 | | Lupoid reaction | j | |
| Diplopia | 1 | | Photosensitivity | 5 | |
| Hypotension | 1 | | Fixed drug eruption | 1 | |
| Hypertension | 1 | | Eczema | Ĺ | |
| Superficial venous | | | Contact dermatitis | 1 | |
| thrombosis | 1 | | Epidermal necrolysis | 1 | |
| Pulmonary embolism | 1 | | Necrosis of skin | • | |
| Gangrene | 1 | | (not from injection) | 1 | |
| Vasculitis | 3 | | Moniliasis | î | |
| Palpitations | 4 | | Psoriasis | 1 | |
| Cardiac arrest | 2 | 2 | Other skin reactions | 327 | |
| Angina | 1 | | Multiple congenital | <i>></i> -1 | |
| Oedema of upper | | | abnormalities | 3 | |
| respiratory tract | 1 | | Congenital spinal deformity | 1 | |
| Bronchospasm | 1 | | Congenital heart disease | 2 | |
| Haemoptysis | 1 | | Oesophageal atresia | 1 | |
| Jaundice | 11 | | Congenital abnormalities | | |
| Abnormal liver function | | | of intestines | 1 | |
| tests | 1 | | Anaphylactic shock | 5 | |
| Duodenal ulcer with | | | Anaphylaxis | 1 | |
| perforation | 1 | 1 | Arthralgia | 4 | |
| Enteritis | 1 | | Pyrexia | 2 | |
| Colitis | 1 | | | | |

| Prescriptions | (EC 10) | for | 1968 | 5.356.000 |
|---------------|---------|-----|------|-----------|
| 11 | 11 | 11 | 1969 | 6,588,000 |
| 11 | 1) | 11 | 1970 | 7,948,000 |

ANTIB TOTICS

Methicillin (70017)

'Celbenin'

Total reports March 1965-October 1971 3 Reports not listed 1

| | Total | Deaths |
|-------------|-------|--------|
| Neutropenia | 1 | |
| Jaundice | 1 | |

Carbenicillin (70019)

'Pyopen'

Total reports October 1968-October 1971 3
Reports not listed Nil

| | Total | Deaths |
|------------|-------|--------|
| Leucopenia | 1 | |
| Headache | 1 | |
| Jaundice | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 1,000 |
|---------------|---------|-----|------|-------|
| 11 | П | 11 | 1969 | 1,000 |
| H | tt | tt | 1970 | 1,000 |

Cephaloridine (70125)

'Ceporin'

Total reports December 1964-October 1971 80 (8 fatal) Reports not listed 4 (2 fatal)

| | Total | Deaths |
|-----------------------|-------|--------|
| Thrombocytopenia | 1 | |
| Leucopenia | 2 | |
| Agranulocytosis | 5 | |
| Neutropenia | 2 | |
| Coomb's test positive | 8 | |
| Encephalitis | 2 | 1 |
| Oculogyric crisis | 1 | |
| Convulsion | 1 | 1 |
| Syncope | 1 | |
| Gait disorder | 2 | |
| Abnormal movements | 1 | |
| Retinitis | 1 | |
| Visual disturbance | 1 | |
| Diplopia | 1 | |
| Nerve deafness | 2 | |
| Hypotension | 1 | |
| Gangrene | 1 | |
| Jaundice | 1 | 1 |
| Nephropathy | 1 | |
| Renal failure | 4 | 2 |
| Uraemia | 1 | |
| Oliguria | 1 | |
| Anuria | 2 | 1 |
| Urticaria | 10 | |
| Morbilliform rash | 3 | |
| Eczema | 3 | |
| Alopecia | 1 | |
| Lichenoid | 1 | |
| Other skin reactions | 12 | |
| Anaphylactic shock | 1 | |
| Anaphylaxis | 1 | |
| Overdose | 1 | |

Cephalothin (70126)

'Keflin'

Total reports September 1969-October 1971 2 Reports not listed Nil

| | Total | Deaths |
|-------------------------------|-------|--------|
| Abnormal taste | 1 | |
| Superficial venous thrombosis | 1 | |

Cephalexin (70127)

'Ceporex', 'Keflex'

Total reports February 1970-October 1971 16 Reports not listed 1

| | Total | Deaths |
|-------------------------|-------|--------|
| Gout | 1 | |
| Memory impairment | 1 | |
| Neuritis | 1 | |
| Jaundice | 1 | |
| Abnormal liver function | | |
| tests | 1 | |
| Dental caries | 1 | |
| Nausea and vomiting | 1 | |
| Urticaria | 2 | |
| Purpura | 1 | |
| Erythema multiforme | - 1 | |
| Eczema | 1 | |
| Other skin reaction | 1 | |
| Anaphylactic shock | 1 | |
| Arthralgia | 1 | |

Fusidic Acid (70135)

'Fucidin', 'Fucidin VP'

Total reports July 1964-October 1971 26 (3 fatal) Reports not listed 1

| | Total | Deaths |
|-------------------------------|-------|--------|
| Fluid retention | 1 | |
| Leucopenia | 1 | |
| Agranulocytosis | | |
| Haemolytic anaemia | | |
| Aplastic anaemia | 1 | |
| Depression | 1 | |
| Retinitis | 1 | |
| Superficial venous thrombosis | 1 | |
| Jaundice | 4 | 2 |
| Diarrhoea | 1 | |
| Nausea and vomiting | 1 | |
| Renal failure | 1 | 1 |
| Morbilliform rash | 1 | |
| Contact dermatitis | 1 | |
| Alopecia | 1 | |
| Localised skin reaction | | |
| (not from injection) | 4 | |
| Other skin reactions | 3 | |
| | | |

Streptomycin (70601)

'Crystamycin', 'Cremostrep', 'Distavone', 'Guanimycin', 'Orastrep'
'Soluvone', 'Streptaquaine', 'Strepolin', 'Streptotriad', 'Sulphamagna'

Total reports March 1964-October 1971 104 (14 fatal)
Reports not listed 20 (6 fatal)

| | Total | Deaths | | Total | Deaths |
|-------------------------|-------|--------|--------------------------|-------|--------|
| Hypothyroidism | 1 | | Gangrene | 1 | |
| Gout | 1 | | Jaundice | 14 | 4 |
| Oedema | 2 | | Abnormal liver function | | |
| Avitaminosis | 1 | | tests | 2 | |
| Thrombocytopenia | 2 | | Peptic ulcer | 1 | 1 |
| Leucopenia | 1 | | Stomatitis | 1 | |
| Aplastic anaemia | 3 | 1 | Nausea and vomiting | 1 | |
| Hypoplastic anaemia | 1 | | Nephropathy | 1 | |
| Encephalitis | 1 | | Renal failure | 1 . | |
| Neuropathy | 1 | | Urticaria | 3 | |
| Paralysis | 1 | | Erythema multiforme | 2 | |
| Gait disorder | 1 | | Erythema nodosum | 1 | |
| Paraesthesia | 1 | | Exfoliative dermatitis | 1 | |
| Spasticity | 1 | | Lupoid reaction | 1 | |
| Sensory disturbance | 1 | | Epidermal necrolysis | 1 | 1 |
| Conjunctivitis | 1 | | Other skin reactions | 16 | |
| Visual disturbance | 1 | | Congenital abnormality | 1 | |
| Scotoma | 1 | | Anaphylactic shock | 3 | 1 |
| Werve deafness | 1 | | Anaphylaxis | 1 | |
| Venous thrombosis, site | | | Pyrexia | 3 | |
| not stated | 1 | | Fibrosis following | | |
| Thrombophlebitis | 1 | | intra-muscular injection | 4 | |

| Prescriptions | (EC 10) | for | 1968 | 972,000 |
|---------------|---------|-----|------|---------|
| Ħ | 11 | п | 1969 | 847,000 |
| 11 | 0 | 11 | 1970 | 694,000 |

Streptoduocin (70603)

'Dimycin', 'Mixtamycin'

Total reports July 1965-October 1971 4 Reports not listed Nil

| | Total | Deaths |
|-------------------------------|-------|--------|
| Parkinsonism | 1 | |
| Abnormal liver function tests | 1 | |

ANTIBIOTICS Neomycin (70606)^x

Total reports July 1964-October 1971 64 (1 fatal) Reports not listed 13

| | Total | Deaths |
|-----------------------------|-------|--------|
| Oedema | 2 | |
| Thrombocytopenia | 1 | |
| Haemolytic anaemia | | |
| Hypoprothrombinaemia | 1 | |
| Paralysis | 1 | |
| Syncope | 1 | |
| Lymphadenopathy | 1 | |
| Headache | 2 | |
| Conjunctivitis | 2 | |
| Nerve deafness | 4 | |
| Cardiac arrest | 1 | 1 |
| Oedema of upper respiratory | | |
| tract | 1 | |
| Jaundice | 1 | |
| Glossitis | 1 | |
| Nausea and vomiting | 1 | |
| Nephrotic syndrome | 1 | |
| Vaginitis | 1 | |
| Urticaria | 6 | |
| Erythema nodosum | 1 | |
| Eczena | 2 | |
| Contact dermatitis | 5 | |
| Localised skin reaction | | |
| (not from injection) | 5 | |
| Pruritus | 2 | |
| Other skin reactions | 6 | |
| Anaphylactic shock | 1 | |

Neomycin is present in numerous topical preparations
Prescription estimates not available

Kanamycin (70608)

'Kannasyn', 'Kanfortrex', 'Kantrexil'

Total reports July 1964-October 1971 15 Reports not listed 1

| | Total | Deaths |
|----------|-----------------------|--------|
| Oedema | 2 1 1 2 5 | |
| Tinnitus | 1 1 1 | |

Gentamycin (70609)

'Cidomycin', 'Gentacin', 'Gentisone'

Total reports March 1967-October 1971 24 (2 fatal)
Reports not listed 2 (1 fatal)

| | Total | Deaths |
|-------------------------|-------|--------|
| Tetany | 1 | |
| Agranulocytosis | 1 | 1 |
| Gait disorder | 1 | |
| Nephropathy | 2 | |
| Nephrotic syndrome | 1 | |
| Urticaria | 1 | |
| Contact dermatitis | 10 | |
| Pemphigoid | 1 | |
| Necrosis of skin | | |
| (not from injection) | 1 | |
| Localised skin reaction | | |
| (not from injection) | 1 | |
| Other skin reactions | 2 | |

| Prescriptions | (EC 10) | for | 1968 | 151,000 |
|---------------|---------|-----|------|---------|
| 11 | 11 | 11 | 1969 | 210,000 |
| п | п | 11 | 1970 | 305,000 |

Viomycin (70610)

'Viocin', 'Viomycin P', 'Vionactane'

Total reports October 1965-October 1971 4

Reports not listed Nil

| | Total | Deaths |
|-------------------------|-------|--------|
| Aplastic anaemia | 1 | |
| Visual disturbance | 1 | |
| Nephropathy | 1 | |
| Congenital abnormaility | 1 | |
| | | |

| Prescriptions | (EC 10) | for | 1968 | under | 1,000 |
|---------------|---------|-----|------|-------|-------|
| 11 | 19 | 11 | 1969 | 17 | 1,000 |
| 11 | 11 | 11 | 1970 | W | 1,000 |

Cycloserine (70615)

Total reports June 1964-October 1971 42 Reports not listed 3

| | Total | Deaths |
|--------------------------|-------|--------|
| Hypothyroidism | 1 | |
| Weight-gain | 1 | |
| Gout | 1 | |
| Haemolytic anaemia | 2 | |
| Psychosis | 1 | |
| Mania | 1 | |
| Mental disorder | 2 | |
| Impotence | 1 | |
| Paralysis | 1 | |
| Convulsion | 4 | |
| Somnolence | 2 | |
| Cerebrovascular disorder | -1 | |
| Tremor | 1 | |
| Visual disturbance | 4 | |
| Vertigo | 1 | |
| Tachycardia | 1 | |
| Jaundice | 2 | |
| Nephropathy | 1 | |
| Uraemia | 1 | |
| Albuminuria | 1 | |
| Abortion | 2 | |
| Urticaria | 1 | |
| Purpura | 1 | |
| Exfoliative dermatitis | 1 | |
| Acne | 1 | |
| Other skin reactions | 2 | |
| Reaction after | | |
| consuming alcohol | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 15,000 |
|---------------|---------|-----|------|--------|
| 11 | 11 | 11 | 1969 | 16,000 |
| 11 | 11 | 12 | 1970 | 13,000 |

Rifampicin (70650)

'Rifadin', 'Rimactane'

Total reports June 1969-October 1971 54 (5 fatal) Reports not listed 9

| | Total | Deaths |
|-------------------------------|-------|--------|
| Hyperlipaemia | 1 | |
| Thrombocytopenia | 2 | |
| Leucopenia | 1 | |
| Leukaemia | 1 | |
| Neuropathy | 1 | |
| Convulsion | 1 | |
| Somnolence | 1 | |
| Coronary occlusion | 1 | J. |
| Jaundice | 23 | 3 |
| Cirrhosis | 1 | 1 |
| Abnormal liver function tests | 4 | |
| Abdominal pain | 1 | |
| Urticaria | 1 | |
| Purpura | 1 | |
| Exfoliative dermatitis | 1 | |
| Alopecia | 1 | |
| Other skin reactions | 3 | |
| | | |

Chloramphenicol (70701)

'Alficetyn', 'Chlormytol', 'Chloromycetin', 'Chlorcetin', 'Ginetris'
'Kemicetine', 'Otophen', 'Otopred', 'Vasocidin'

Total reports April 1964-October 1971 64 (29 fatal) Reports not listed 3

| | Total | Deaths |
|---------------------------|-------|--------|
| Oedema | 1 | |
| Thrombocytopenia | 3 | 1 |
| Agranulocytosis | 5 | 3 |
| Pancytopenia | 3 | 3 |
| Aplastic anaemia | 24 | 19 |
| Optic neuritis | 1 | |
| Congunctivitis | 2 | |
| Deep venous thrombosis | 1 | |
| Jaundice | 1 | 1 |
| Vaginitis | 1 | |
| Urticaria | 2 | |
| Angioneurotic oedema | 1 | |
| Morbilliform rash | 1 | 1 |
| Eczema | 1 | |
| Contact dermatitis | 2 | |
| Localised skin reactions | 2 | |
| Other skin reactions | 7 | |
| Congenital abnormality | 1 . | 1 |
| Fibrosis following intra- | | |
| muscular injection | 2 | |
| | | |

| Prescriptions | (EC 10) | for | systemic | chloramphenicol | 1968 | 149,000 | Others (e | eg topical) | 898,000 |
|---------------|---------|-----|----------|-----------------|------|---------|-----------|-------------|-----------|
| 11 | Ħ | 11 | 13 | H . | 1969 | 99,000 | H . | 11 | 926,000 |
| n | H | 11 | 11 | 11 | 1970 | 58,000 | n | 18 | 1,299,000 |

Tetracycline (70720)

'Achromycin', 'Albamycin-T', 'Bristrex', 'Chymocyclar', 'Clinitetrin', 'Co-caps Tetracycline', 'Deteclo', 'Economycin', 'Mysteclin', 'Servicin', 'Sigmamycin', 'Siltetrin', 'Steclin', 'Telotrex' 'Tetrachel', 'Tetrex', 'Totomycin', 'Tetracyn', 'Uropol'

Total reports May 1964-October 1971 239 (27 fatal) Reports not listed 41 (10 fatal)

| | Total | Deaths | Total Deaths |
|-------------------------|-------|--------|--------------------------|
| Hypothyroidism | 1 | | Glossitis 2 |
| Pancreatic disorder | 1 | | Gastro-intestinal |
| Oedema | 6 | 1 | haemorrhage 1 |
| Thrombocytopenia | 8 | 2 | Constipation 1 |
| Leucopenia | 2 | | Diarrhoea 3 |
| Agranulocytosis | 5 | 3 | Nausea and vomiting 10 |
| Pancytopenia | 2 | | Abdominal pain 2 |
| Haemolytic anaemia | 1 | | Nephropathy 1 |
| Aplastic anaemia | 3 | | Retention of urine 1 |
| Coagulation defect | 1 | 1 | Vaginitis 1 |
| Hypoprothrombinaemia | 1 | | Urticaria 16 |
| Depression | 1 | | Angioneurotic oedema 4 |
| Delirium | 1 | | Purpura 3 |
| Neuritis | 1 - | | Morbilliform rash 2 |
| Syncope | 1 | | Erythema multiforme 1 |
| Somnolence | . 3 | | Erythema nodosum 4 |
| Cerebral oedema | 1 | | Exfoliative dermatitis 2 |
| Headache | 7 | | Lupoid reaction 1 |
| Gait disorder | 1 | | Photosensitivity 1 |
| Paraesthesia | 3 | | Fixed drug eruption 1 |
| Stammer | 1 | | Eczema 2 |
| Giddiness | 3 | | Epidermal necrolysis 1 |
| Optic neuritis | 1 | | Necrosis of skin (not |
| Visual disturbance | 3 | | from injection) |
| Diplopia | 1 | | Pigment change 2 |
| Amblyopia | 1 | | Moniliasis 1 |
| Vertigo | 1 | | Pruritus |
| Taste abnormality | 1 | | Other skin reactions 28 |
| Disorder of sense | | | Multiple congenital |
| of smell | 1 | | abnormalities 2 |
| Tachycardia | 1 | | Congenital abnormality |
| Cardia arrest | 1 | 1 | of the eye 1 |
| Pharyngitis | 1 | | Cleft-palate 1 |
| Haemoptysis | 1 | | Limbs deformity 1 |
| Jaundice | 15 | 9 | Oesophageal atresia 1 |
| Hepatomegaly not | | | Anaphylactic shock 3 |
| jaundical | 1 | | Anaphylaxis 1 |
| Gastric ulcer | | | Rigor 1 |
| with haemorrhage | 1 | | Arthralgia 2 |
| Discolouration of teeth | 6 | | |
| Stomatitis | 1 | | |
| Salivary gland swelling | 1 | | |

| Prescriptions | (EC 10) | for | 1968 | 5,896,000 |
|---------------|---------|-----|------|-----------|
| VI | Ħ | H | 1969 | 5,556,000 |
| Ħ | II. | 17 | 1970 | 4.904.000 |

Chlortetracycline (70722)

'Aureocort', 'Aureomycin', 'Detaclo'

Total reports June 1964-October 1971 12 (1 fatal) Reports not listed 2

| | Total | Deaths |
|-------------------------|-------|--------|
| Aplastic anaemia | 1 | 1 |
| Headache | 1 | |
| Cataract | 1 | |
| Discolouration of teeth | 1 | |
| Abdominal pain | 1 | |
| Skin reactions | 5 | |

Demethylchlortetracycline (70724)

'Detaclo', 'Lederaycin', 'Lederstatin'

Total reports April 1964-October 1971 87 (3 fatal)
Reports not listed 7 (2 fatal)

| | Total | Deaths |
|------------------------|-------|--------|
| | | |
| Oedema | 2 | |
| Hypokalaemia | 1 | 1 |
| Aplastic anaemia | 1 | |
| Psychosis | 2 | |
| Mental disorder | 1 | |
| Debility | 3 | |
| Syncope | 1 | |
| Headache | 2 | |
| Cataract | 1 | |
| Vertigo | 1 | |
| Bronchospasm | 1 | |
| Dental caries | 1 | |
| Stomatitis | 1 | |
| Diarrhoea | 1 | |
| Abdominal pain | 1 | |
| Urticaria | 1 | |
| Angioneurotic Oedema | 1 | |
| Purpura | 1 | |
| Photosensitivity | 49 | |
| Fixed drug eruption | 1 | |
| Other skin reactions | 5 | |
| Congenital abnormality | 1 | |
| Arthralgia | 1 | |
| | | |

| Prescriptions | (EC 10) | for | 1968 | 877,000 |
|---------------|---------|-----|------|---------|
| 11 | п | 17 | 1969 | 682,000 |
| 11 | tt . | 11 | 1970 | 753,000 |

Methacycline (70726)

'Rondomycin'

Total reports August 1964-October 1971 15
Reports not listed Nil

| Prescriptions | (EC 10) | for | 1968 | 339,000 |
|---------------|---------|-----|------|---------|
| Ħ | H | 11 | 1969 | 151,000 |
| 11 | II 4 | 11 | 1970 | 130,000 |

Oxytetracycline (70728)

'Berkmycen', Clinimycin', 'Galenomycin', 'Ia-Loxine', 'Imperacin', 'Oxatets'
'Oxydon','Oxymycin', 'Stecsolin', 'Terramycin', 'Terra-Cortril'

Total reports March 1964-October 1971 1/47 (5 fatal) Reports not listed 29 (3 fatal)

| Total Dea | ths To | tal Deaths |
|------------|---|--|
| Gout | Diarrheck | 3 4 1 1 1 1 1 2 3 1 1 2 7 1 2 29 3 |
| Dyspnoea | Reduction deformity of limbs Congenital abnormality of genitalia gonads | 3 |
| Stomatitis | Intrauterine death | 1 |
| | intra-muscular injection | 1 |

| Prescriptions | (EC 10) | for | 1968 | 7,977,000 |
|---------------|---------|-----|------|-----------|
| Н | 19 | 11 | 11 | 8,424,000 |
| H | 11 | 11 | 11 | 8,955,000 |

Lymecycline (70730)

'Armyl', 'Tetralysal'

Total reports June 1964-October 1971 7 (1 fatal) Reports not listed 1 (1 fatal)

| | Total | Deaths |
|----------|-------------|--------|
| Migraine | 1 1 4 | |

| Prescriptions | (EC 10) | for | 1968 | 77,000 |
|---------------|---------|-----|------|---------|
| 11 | H | II. | 1969 | 134,000 |
| H . | п | 11 | 1970 | 94,000 |

Doxycycline (70732)

'Vibramycin'

Total reports November 1965-October 1971 19 (1 fatal) Reports not listed 1

| | Total | Deaths |
|-----------------------------------|-------|--------|
| Menstrual irregularities | 1 | |
| Oedema | 1 | |
| Tetany | 1 | |
| Aplastic anaemia | 1 | 1 |
| Oedema of upper respiratory tract | 1 | |
| Oesophagitis | 5 | |
| Nausea and vomiting | 3 | · |
| Skin reactions | 4 | |
| Anaphylactic shock | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 55,000 |
|---------------|---------|-----|------|---------|
| 11 | 1) | 11 | 1969 | 89,000 |
| п | H | 11 | 1970 | 166,000 |

Clomocycline (70740)

'Megaclor'

Total reports July 1967-October 1971 5
Reports not listed NIL

| | Total | Deaths |
|-----------|-------|--------|
| Oedema | 1 | |
| Glossitis | 1 | |
| Diarrhoea | | |

| Prescriptions | (EC 10) | for | 1968 | 150,000 |
|---------------|---------|------|------|---------|
| н | n | 11 | 1969 | 128,000 |
| н | 11 | - 11 | 1970 | 140,000 |

Erythromycin (70801)

Erycen, *Erythrocin*, *Erythromid*, *Erythroped*, *Ilosone*, *Ilotycin*

 Total reports June 1964-October 1971
 121 (7 fatal)

 Reports not listed
 17 (2 fatal)

| | Total | Deaths |
|-------------------------------|-------|--------|
| Oedema | 1 | |
| Thrombocytopenia | 3 | 1 |
| Haemolytic anaemia | 2 | |
| Aplastic anaemia | 2 | 1 |
| Dependence | 1 | |
| Confusional state | 3 | |
| Mental disorder | 1 | |
| Convulsion | 1 | |
| Syncope | 1 | |
| Headache | 1 | |
| Giddiness | 1 | |
| Palpitations | 1 | |
| Jaundice | 29 | 1 |
| Abnormal liver function tests | 2 | |
| Proctitis | 1 | |
| Discolouration of teeth | 1 | |
| Gastro-intestinal haemorrhage | 1 | |
| Diarrhoea | 2 | |
| Nausea and vomiting | 7 | |
| Abdominal pain | 4 | |
| Renal failure | 1 | 1 |
| Urticaria | 7 | |
| Purpura | 4 | |
| Mobilliform rash | 2 | |
| Photosensitivity | 3 | |
| Fixed drug eruption | 1 | |
| Other skin reactions | 17 | |
| Congenital abnormality | 2 | |
| Rigor | 1 | |
| Pyrexia | 1 | 1 |

| Prescriptions | (EC 10) | for | 1968 | 1,236,000 |
|---------------|---------|-----|------|-----------|
| n | II | Ħ | 1969 | 1,541,000 |
| 11 | n | 11 | 1970 | 1.876,000 |

Triacetyloleandomycin (70804)

'Evramycin'

Total reports September 1965-October 1971 1
Reports not listed NIL

Total Deaths

Nausea and vomiting 1

| Prescriptions | (EC 10) | for | 1968 | 1,000 |
|---------------|---------|-----|------|-------|
| II . | 11 | п | 1969 | 1,000 |
| 11 | 92 | H | 1970 | 8,000 |

Novobiocin (70905)

'Albamycin', 'Cathomycin', 'Cathopen', 'Novobiocin'

Total reports July 1964-October 1971 15

Reports not listed 2

| | Total | Deaths |
|------------------------|-------|--------|
| Stammer | 1 | |
| Nerve deafness | 1 | |
| Jaundice | 2 | |
| Nephropathy | 1 | |
| Urticaria | 1 | |
| Mobilliform rash | 1 | |
| Exfoliative dermatitis | 1 | |
| Pruritus | 1 | |
| Other skin reactions | 4 | |

| Prescriptions | (EC 10) | for | 1968 | 234,000 |
|---------------|---------|-----|------|---------|
| н | H | Ħ | 1969 | 225,000 |
| 11 | н | H | 1970 | 112,000 |

Framycetin (70908)*

'Enterfram', 'Framygen', 'Framycort', 'Neo Sulfazon'
'Soframycin', 'Sofracort', 'Sofradex'

Total reports April 1965-October 1971 6
Reports not listed NIL

Total Deaths

Conjunctivitis 2

Skin reactions 4

*Reaction were to topical preparations

| Prescriptions | (EC 10) | for | 1968 | 467,000 |
|---------------|---------|-----|------|-----------|
| Н | 11 | | | 946,000 |
| 11 | н | 11 | 1970 | 1.127.000 |

Lincomycin (70910)

'Lincocin', 'Mycivin'

Total reports November 1964-October 1971 95 (5 fatal) Reports not listed 6

| | Total | Deaths |
|--|-------|--------|
| Thrombocytopenia | 1 | |
| Agranulocytosis | ī | |
| Aplastic anaemia | 1 | 1 |
| Leukaemia | 1 | _ |
| Neuritis | ī | |
| Headache | 2 | |
| Sweating | 1 | |
| • | 1 | |
| Flushing | | |
| Vertigo | 1 | |
| Bronchospasm | 1 | |
| Jaundice | 3 | 2 |
| Gastritis | 1 | |
| Protitis | 2 | |
| Ileus | 1 | |
| Diarrhoea | 34 | |
| Renal failure | 1 | 1 |
| Haematuria | 2 | |
| Urticaria | 11 | |
| Angioneurotic oedema | 1 | |
| Purpura | 2 | 1 |
| Morbilliform rash | 2 | |
| Erythema nodosum | 1 | |
| Exfoliative dermatitis | 1 | |
| Eczema | 1 | |
| Pruritus | 1 | |
| Other skin reactions | 14 | |
| COMOT DEFE CONCOLORS \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ | | |

| Prescriptions | (EC 10) | for | 1968 | 269,000 |
|---------------|---------|-----|------|---------|
| 11 | 11 | 11 | 1969 | 256,000 |
| . 11 | н | 11 | 1970 | 176,000 |

Clindamycin (70911)

'Dalacin C'

Total reports January 1970-October 1971 17 Reports not listed 3

| | Total | Deaths |
|---------------------|-------|--------|
| Dyspnoea | 1 | |
| Colitis | 1 | |
| Glossitis | 1 | |
| Nausea and vomiting | 3 | |
| Abdominal pain | 1 | |
| Urticaria | | |
| Skin reactions | 5 | |

Capreomycin (70915)

Total reports November 1964-October 1971 49 (4 fatal) Reports not listed 2 (1 fatal)

| | Total | Deaths |
|-------------------------------|-------|--------|
| at | , | 1 |
| Gout | 1 | , |
| Aplastic anaemia | 1 | |
| Headache | 3 | |
| Gait disorder | 1 | |
| Visual disturbance | 5 | |
| Nerve deafness | 2 | |
| Tinnitis | 2 | |
| Labyrinthitis | 1 | |
| Cirrhosis | 1 | 1 |
| Abnormal liver function tests | 1 | |
| Renal failure | 3 | 2 |
| Uraemia | 9 | |
| Albuminuria | 3 | |
| Frequency | 1 | |
| Polyuria | 1 | |
| Urticaria | 1 | |
| Purpura | 1 | |
| Other skin reactions | 10 | |

Tyrothricin (with benzocaine) (70951)

'Tyrosolven', 'Tyrozets'

Total reports June 1964-October 1971 10 Reports not listed 1

| | Total | Deaths |
|-----------------------------------|-------|--------|
| Oedema of upper respiratory tract | 1 | |
| Jaundice | 1 | |
| Stomatitis | 1 | |
| Glossitis | 1 | |
| Skin reactions | 3 | |
| Congenital abnormality | 1 | |
| Anaphylaxis | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 212,000 |
|---------------|---------|-----|------|---------|
| n | II | n | 1969 | 175,000 |
| 11 | 11 | Ħ | 1970 | 192,000 |

Gramicidin (70952)

'Gromidin', 'Graneodin', 'Negamycin', 'Neosporin'
'Soframycin', 'Sofracort', 'Sofradex', 'Tri-Adcortyl'

Total reports April 1964-October 1971 4
Reports not listed 1

Total Deaths

Skin reactions 3

| Prescriptions | (EC 10) | for | 1968 | 551,000 |
|---------------|---------|-----|------|---------|
| 11 | Ħ | Ħ | 1969 | 463,000 |
| 11 | H | H | 1970 | 836,000 |

Bacitracin (70953)

'Cicatrin', 'Dermamed', 'Diplomycin', 'Framyspray', 'Hydroderm', 'Neobacrin', 'Neolate'
'Nivebaxin', 'Ototrips', 'Polybactrin', 'Polyfax', 'Sentest Bacitracin', 'Tetrazets'

Total reports February 1965-October 1971 10
Reports not listed 2

| | Total | Deaths |
|-----------------------------|-------|--------|
| Oedema of upper respiratory | | |
| tract | 1 | |
| Jaundice | 1 | |
| Glossitis | 1 | |
| Skin reactions | 5 | |

| Prescriptions | (EC 10) | for | 1968 | 522,000 |
|---------------|---------|-----|------|---------|
| н | 11 | 11 | 1969 | 497,000 |
| н | 11 | н | 1970 | 622,000 |

Colistin (70955)

'Colomycin'

Total reports September 1964-October 1971 16 (3 fatal) Reports not listed Nil

| | Total | Deaths |
|--------------------------|-------|--------|
| Thrombocytotpenia | 1 | 1 |
| Agranulocytosis | 1 | |
| Hypoprothrombinaemia | 1 | |
| Paralysis | 1 | |
| Gait disorder | 1 | |
| Jaundice | 2 | |
| Renal failure | 1 | 1 |
| Skin reactions | 6 | |
| Congenital abnormality | 1 | 1 |
| Fibrosis following | | |
| intra-muscular injection | 1 | |
| | | |

| Prescriptions | (EC 10) | for | 1968 | 3,000 |
|---------------|---------|-----|------|-------|
| 11 | П | Н | 1969 | 3,000 |
| 11 | 11 | п | 1970 | 6,000 |

Polymixin (70956)

'Aerosporin', 'Diplomycin', 'Framyspray', 'Neosporin', 'Otosporin', 'Ototrips' 'Polybactrin', 'Polyfax', 'Terramycin with Polymixin', 'Unioptal', 'Vasocidin'

Total reports February 1965-October 1971 10 Reports not listed 2

| | Total | Deaths |
|---|-----------------------|--------|
| Syncope Conjunctivitis Nerve deafness Nausea and vomiting Nephropathy Skin reactions | 1 1 2 1 1 | |

| Prescriptions | (EC 10) | for | 1968 | 928,000 |
|---------------|---------|-----|------|---------|
| H 1 | н | 11 | 1969 | 878,000 |
| 11 | 11 | 11 | 1970 | 992,000 |

Sulphomyxin (70957)

'Thiosporin'

Total reports August 1967-October 1971 l Nil Reports not listed

> Total Deaths

Inflammation following intra-muscular injection 1

SULPHONAMIDES

Sulphaguanidine (71001)

'Guanimycin', 'Ivax', 'Neo Sulfazon'

Total reports August 1964-October 1971 5 (1 fatal)
Reports not listed 3

| Prescriptions | (EC 1 | 0) for | 1968 | 839,000 |
|---------------|-------|--------|------|---------|
| Ħ | 11 | H | 1969 | 813,000 |
| H | 29 | 11 | 1970 | 717,000 |

Phthalylsulphathiazole (71005)

'Neo Sulfazon', 'Sulfathalidine', 'Sulphamagna', 'Thalazole'

Total reports January 1965-October 1971 4

Reports not listed Ni:

| | Total | Deaths |
|------------------------|-------|--------|
| Skin reaction | 2 | |
| Congenital abnormality | 1 | |
| Pyrexia | 1 | |

| Presceiptions | (EC 10) | for | 1968 | 71,000 |
|---------------|---------|------|------|---------|
| H | 11 | ft . | 1969 | 60,000 |
| Ħ | 11 | 11 | 1970 | 135,000 |

Sulphanilamide (71007)

Tampovagan PSSt

Total reports November 1965-October 1971 2
Reports not listed Nil

Total Deaths
Syncope 2

 Prescriptions (EC 10) for 1968
 21,000

 #
 #
 # 1969
 11,000

 #
 # 1970
 12,000

Sulphathiazole (71008)

'Penitriad', 'Streptotriad', 'Sulphatriad', Sultrin', 'Tampovagan PSS', 'Thiazamide'

Total reports June 1964-October 1971 15 (1 fatal)
Reports not listed Nil

| | Total | Deaths |
|---------------------|-------|--------|
| Agranulocytosis | 1 | 1 |
| Syncope | 2 | |
| Vasculitis | 1 | |
| Stomatitis | 1 | |
| Urticaria | 5 | |
| Erythema multiform | 1 1 | |
| Erythema nodosum | 2 | |
| Fixed drug eruption | 1 | |
| Other skin reaction | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 335,000 |
|---------------|---------|-----|------|---------|
| 11 | 12 | 11 | 1969 | 348,000 |
| Ħ | Ħ | 11 | 1970 | 547,000 |

Sulphamethizole (71012)

'Urolucosil'

Total reports November 1964-October 1971 29 (2 fatal)

Reports not listed 7

| | Total | Deaths |
|------------------------------|-------|--------|
| Thrombocytopenia | 1 | |
| Laucopenia | 1 | 1 |
| Agranulocytosis | 1 | |
| Pancytopenia | 1 | |
| Aplastic anaemia | 1 | 1 |
| Dystonia | 1 | |
| Paraesthesia | 2 | |
| Vertigo | 1 | |
| Nausea and vomiting | 1 | |
| Urticaria | 1 | |
| Purpura | 1 | |
| Photosensitivity | 2 | |
| Pigment change | 1 | |
| Other skin reactions ••••••• | 5 | |
| Arthralgia | í | |
| Muscle pain | 1 | |
| | | |

| Prescriptions | (EC 10) | for | 1968 | 814,000 |
|---------------|---------|-----|------|---------|
| 11 | ti | II | 1969 | 746,000 |
| ŧŧ. | it | 11 | 1970 | 778,000 |

Sulphaphenazole (71014)

'Orisulf'

Total reports August 1966-October 1971 6 (2 fatal)
Reports not listed Nil

| | Total | Deaths |
|--------------------|-------|--------|
| Agranulocytosis | 1 | 1 |
| Haemolytic anaemia | 1 | |
| Abdominal pain | 1 | |
| Skin reactions | 3 | 1 |

| Prescriptions | (EC | 10) | for | 1968 | 87,000 |
|---------------|-----|-----|-----|------|--------|
| II . | Н | | 11 | 1969 | 61,000 |
| 11 | п | | 11 | 1970 | 33,000 |

Sulphamethoxazole (71017)

'Gantanol'

Total reports October 1964-October 1971 7
Reports not listed Nil

| | Total | Deaths |
|----------------|-------|--------|
| Oedema | 1 | |
| Tremor | 1 | |
| Giddiness | 1 | |
| Pharyngitis | 1 | |
| Skin reactions | 3 | |

| Prescriptions | (EC 10) | for | 1968 | 101,000 |
|---------------|---------|-----|------|---------|
| H | II | 11 | 1969 | 96,000 |
| H | 11 | 11 | 1970 | 56,000 |

Sulphamethoxazole (71017) with Trimethoprim (71925)

Bactrim', Septrin'

Total reports November 1968-October 1971 676 (19 fatal) Reports not listed 32

| | Total | Deaths | | Total | Deaths |
|---|-------|--------|--------------------------|-------|--------|
| Gout ************************************ | 1 | | Jaundice | 28 | 1 |
| Oedema | 6 | | Abnormal liver | | |
| Thrombocytopenia | 20 | 3 | function tests | 1 | |
| Leucopenia | 15 | | Gastric ulcer | | |
| Agranulocytosis | 11 | 2 | with perforation | 1 | 1 |
| Neutropenia | 4 | 2 | Duodenal ulcer | | |
| Pancytopenia | 3 | 1 | with perforation | 1 | 1 |
| Haemolytic anaemia | 1 | • | Colitis | 1 | 1 |
| Aplastic anaemia | i. | 1 | Stomatitis | 9 | |
| Hypoplastic anaémia | 1 | | Salivary gland swelling | 1 | |
| Macrocytic anaemia | 4 | | Glossitis | 26 | |
| Coagulation defect | 3 | 1 | Gastro-intestinal | | |
| Leukaemia | 2 | 2 | haemorrhage | 3 | |
| Mania | 1 | 2 | Diarrhoea | 3 | |
| Depression | 4 | | Nausea and vomiting | 14 | |
| Confusional state | 4 | | Abdominal pain | 13 | |
| Hallucinations | 11 | | Dyspepsia | 1 | |
| Intellectual impairment | 1 | | Nephrotic syndrome | 1 | |
| Mental disorder | 2 | | Uraemia | 3 | 1 |
| | 2 | | Dysuria | 1 | • |
| Debility | 1 | | Oliguria | 1 | |
| Neuropathy | 1 | | Anuria | 1 | |
| Neuritis Oculogyric crisis | 1 | | Retention of urine | 1 | |
| Convulsions | 1 | | Urticaria | 66 | |
| Coma | 1 | | Angioneurotic aedema | 5 | |
| Somnolence | 5 | | Purpura | 17 | 1 |
| Headache | 11 | | Morbilliform rash | 45 | 1 |
| Photophobia | 1 | | Erythema multiforme | 5 | • |
| Flushing | 1 | | Stevens Johnson Syndrome | 2 | |
| Generalised weakness | 1 | | Exfoliative dermatitis . | 4 | |
| Tremor | 4 | | Photosensitivity | 10 | |
| Paraesthesia | 1 | | Eczema | 1 | |
| Sleep disorder | 3 | | Epidermal necrolysis | 1 | 1 |
| Abnormal movements | 1 | | Alopecia | 2 | • |
| Giddiness | i. | | Moniliasis | 2 | |
| Visual disturbance | 2 | | Pruritus | 5 | |
| | 1 | | Other skin reactions | 202 | |
| Vertigo | 1 | | Congenital abnormalities | 2 | |
| Cyanosis | 1 | | Anaphylaxis | 2 | |
| Tachycardia | 1 | 1 | Rigor | 2 | |
| Cardia arrest | 1 | | Arthralgia | 2 | |
| Dyspnoea | 1 | | Pyrexia | 3 | |
| Sheezing | | | Muscle pain | 8 | |
| Pharyngitis | 2 | | | | |
| Haemoptysis | 1 | | | | |

| Prescriptions | (EC 10) | for | 1968 | 122,000 |
|---------------|---------|-----|------|-----------|
| 11 | U. | 11 | 1969 | 881,000 |
| 11 | 17 | H | 1970 | 1,178,000 |

Sulphafurazole (71019)

'Gantrisin', 'Novotriad'

Total reports November 1964-October 1971 8 Reports not listed 1

| | Total | Deaths |
|---------------------|-------|--------|
| Flushing | 1 | |
| Nausea and vomiting | 1 | |
| Skin Reactions | 5 | |

| Prescriptions | (EC 10) | for | 1968 | 186,000 |
|---------------|---------|-----|------|---------|
| n | n | 11 | 1969 | 162,000 |
| | 11 | Ħ | 1970 | 116,000 |

Sulphacetamide (71020)

'Albucid', 'Cortucid', 'Ocusol', 'Steravite', 'Sultrin'

Total reports December 1964-October 1971 1
Reports not listed Nil

Total Deaths

Conjunctivities 1

| Prescriptions | (EC 10) | for | 1968 | 775,000 |
|---------------|---------|-----|------|---------|
| ŧ | 11 | H | 1969 | 680,000 |
| 11 | 11 | 11 | 1970 | 855,000 |

Sulphaproxyline (71023)

Dosulf in

Total reports November 1964-October 1971 1

Reports not listed Nil

Total Deaths

Thrombocytopenia

Prescriptions (EC 10) for 1968 9,000

| N N 1969 3,000
| N N 1970 1,000

Sulphasalazine (71026)

'Salazopyrin'

Total reports April 1964-October 1971 71 (3 fatal) Reports not listed 6 (1 fatal)

| | Total | Deaths |
|------------------------|---------------|--------|
| Esinophilia | 1 | |
| Thrombocytopenia | 1 | |
| Leucopenia | 5 | |
| Agranulocytosis | 5 7 | 1 |
| Neutropenia | 3 | 1 |
| Haemolytic anaemia | 10 | |
| Aplastic anaemia | 1 | |
| Hypochromic anaemia | 1 | |
| Macrocytic anaemia | 1 | |
| Emotional change | 1 | |
| Headache | 4 | |
| Paraesthesia | 2 | |
| Giddiness | 1 | |
| Cyanosis | 1 | |
| Jaundice | 3 | |
| Nausea and vomiting | 2 | |
| Abdominal pain | 2 | |
| Dysuria | 1 | |
| Urticaria | 2 | |
| Purpura | 1 | |
| Erythema nodosum | 1 | |
| Photosensitivity | 1 | |
| Other skin reactions | 10 | |
| Congenital abnormality | 1 | |
| Arthralgia | 1 | |
| Pyrexia | 1 | |
| | | |

| Prescriptions | | | | 101,000 |
|---------------|----|------|------|---------|
| tt | W | 11 | 1969 | 115,000 |
| Ħ | 11 | . 17 | 1970 | 124,000 |

Sulphadimidine (71030)

'Cremotresamide', 'Eskacillin Sulpha', 'Novotriad', 'Orastrep'
'Penbritin-KS', 'Penidural-Sulphas', 'Penitriad', 'Streptotriad'
'Sulphamezathine', 'Sulpenin V', 'Suvita', V-Cil-K Sulpha'

Total reports June 1964-October 1971 86 (5 fatal) Reports not listed 8 (1 fatal)

| | Total | Deaths |
|---------------------------|-------|--------|
| Gout | 1 | |
| Oedema | 1 | |
| Thrombocytopenia | 3 | |
| Agranulocytosis | 4 | 3 |
| Neutropenia | 1 | |
| Haemolytic anaemia | 1 | |
| Aplastic anaemia | 2 | |
| Hypoplastic anaemia | 1 | |
| Lymphadenopathy | 1 | |
| Syncope | 1 | |
| Flushing | 1 | |
| Conjunctivitis | 2 | |
| Oedema of upper | | |
| respiratory tract | 1 | |
| Jaundice | 1 | |
| Gastro-intestinal | | |
| haemorrhage | 1 | |
| Stomatitis | 2 . | |
| Glossitis | 1 | |
| Renal failure | 1 | 1 |
| Urticaria | 7 | |
| Angioneurotic oedema | 2 | |
| Purpura | 5 | |
| Morbilliform rash | 9 | |
| Arythema multifor e | 1 | |
| Erythema nodosum | 1 | |
| Photosensitivity | 3 | |
| Eczema | 1 | |
| Other skin reactions | 15 | |
| Congenital abnormalities | 4 | |
| Arthralgia | 1 | |
| Pyrexia | 1 | |
| Carcinoma of breast | 1 | |
| Fibrosis following intra- | | |
| muscular injection | 1 | |
| | | |

| Prescriptions | (EC 10) | for | 1968 | 389.000 |
|---------------|---------|-----|------|---------|
| 11 | 11 | Ħ | 1969 | 369,000 |
| 11 | 11 | 11 | 1970 | 342,000 |

Sulphamerazine (71032)

'Cremotresamide', 'Dosulfin', 'Penidural Sulphas', 'Sulphatriad', 'Trisulphonamide'

Total reports June 1964-October 1971 11
Reports not listed Nil

| | Total | Deaths |
|---------------------|-------|--------|
| Thrombocytopenia | 1 | |
| Vasculitis | 1 | |
| Stomatitis | 11 | |
| Urticaria | 3 | |
| Purpura | 1 | |
| Erythema multiforme | 1 | |
| Erythema nodosum | 1 | |
| Fixed drug eruption | 1 | |
| Other skin reaction | 1 | |

| Prescriptions | (EC 10) | | | 154,000 |
|---------------|---------|----|------|---------|
| 11 | 11 | 11 | 1969 | 189,000 |
| 11 | tt . | | 1970 | |

Sulphadiazine (71036)

'Cremodiazine', 'Cremotresamide', 'Novotriad', 'Penidural-Sulphas'
'Penitriad', 'Streptotriad', 'Sulphamagna', 'Sulphatriad', 'Trisulphonamide'

Total reports June 1964-October 1971 22 Reports not listed Nil

| | Total | Deaths |
|--------------------------|-------|--------|
| Oedema | 1 | |
| Thrombocytopenia | 2 | |
| Leucopenia | 1 | |
| Vasculitis | 1 | |
| Stomatitis | 2 | |
| Uraemia | 2 | |
| Oliguria | 1 | |
| Urticaria | 4 | |
| Erythema multiforme | 1 | |
| Erythema nodosum | 2 | |
| Fixed drug eruption | 1 | |
| Other skin reactions | 2 | |
| Pyrexia | 1 | |
| Fibrosis following | | |
| intra-muscular injection | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 367,000 |
|---------------|---------|-----|------|---------|
| 11 | Ħ | 11 | 1969 | 301,000 |
| 11 | - 11 | 18 | 1970 | 302,000 |

Sulphamethoxydiazine (71037)

'Durenate'

Total reports June 1964-October 1971 20
Reports not listed Nil

| | Total | Deaths |
|--------------------------|-------|--------|
| Stomatitis | 1 | |
| Haematuria | 1 | |
| Urticaria | 1 | |
| Morbilliform rash | 3 | |
| Erythema multiforme | 1 | |
| Stevens Johnson syndrome | 2 | • |
| Other skin reactions | 9 | |
| Fixed drug eruption | 1 | |
| Congenital abnormalities | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 73,000 |
|---------------|---------|-----|------|--------|
| 11 | H | H | 1969 | 60,000 |
| Ħ | 11 | 19 | 1970 | 33,000 |

Sulphadimethoxine (71039)

'Madribon'

Total reports February 1965-October 1971 7 Reports not listed Nil

| | Total | Deaths |
|--------------------|-------|--------|
| Haemolytic anaemia | 1 | |
| Headache | 1 | |
| Jaundice | 3 | |
| Glossitis | 1 | |
| Morbilliform rash | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 53,000 |
|---------------|---------|-----|------|--------|
| н | Н | 17 | 1969 | 42,000 |
| н | Ħ | н | 1970 | 37,000 |

Sulphamethoxypyridazine (71045)

'Lederkyn', 'Midicel'

Total reports March 1964-October 1971 59 (4 fatal) Reports not listed 4

| | Total | Deaths |
|--------------------------|-------|--------|
| Oedema | 2 | |
| Leucopenia | 1 | 1 |
| Neutropenia | 1 | |
| Haemolytic anaemia | 2 | |
| Lymphadenopathy | 1 | |
| Paraesthesia | | |
| Vasculitis | 1 | |
| Myocarditis | 1 | 1 |
| Asthma | 1 | 1 |
| Jaundice | 2 | |
| Dental caries | 1 | |
| Oliguria | 1 | |
| Urticaria | 9 | |
| Purpura | 3 | |
| Morbilliform rash | 2 | |
| Stevens Johnson syndrome | 6 | 1 |
| Exfoliative dermatitis | 2 | |
| Photosensitivity | 2 | |
| Eczema | 1 | |
| Epidermal Necrolysis | 1 | |
| Other skin reactions | 14 | |
| | | |

| Prescriptions | (EC 10) | for | 1968 | 106,000 |
|---------------|---------|-----|------|---------|
| 11 | Ħ | 11 | 1969 | 88,000 |
| 11 | H | 11 | 1970 | 62,000 |

Sulfametopyrazine (71050)

'Kelfizine'

Total reports November 1969-October 1971 2

Reports not listed Nil

Total Deaths
Urticaria 2

Ethionamide (71100)

'Trescatyl', 'Trescazide'

Total reports May 1964-October 1971 37 (3 fatal) Reports not listed 2

| | Total | Deaths |
|-------------------------------|-------|--------|
| Hypoglycaemia | 1 | 1 |
| Gout | 2 | |
| Haemolytic anaemia | 2 | |
| Schizophrenia | 1 | |
| Depression | 2 | |
| Mental disorder | 2 | |
| Encephalitis | 1 | |
| Convulsions | 1 | |
| Headache | 2 | |
| Visual disturbance | 3 | |
| Tinnitus | 2 | |
| Jaundice | 4 | 1 |
| Abnormal liver function tests | 1 | |
| Gastritis | 1 | |
| Gastro-intestinal haemorrhage | 1 | 1 |
| Nausea and vomiting | 2 | |
| Albuminuria | 1 | |
| Skin reactions | 4 | |
| Congenital abnormalities | 2 | |

| Prescriptions | (EC 10) | for | 1968 | 7,000 |
|---------------|---------|-----|------|-------|
| lt . | 11 | п | 1969 | 5,000 |
| 11 | 93 | п | 1970 | 2,000 |

Ethambutol (71101)

'Myambutol'

Total reports March 1968-October 1971 60 (10 fatal) Reports not listed 5 (4 fatal)

| | Total | Deaths |
|-------------------------------|-------|--------|
| Gynaecomastia (male) | 1 | |
| Tetany | 1 | |
| Thrombocytopenia | 1 | |
| Leucopenia | 1 | |
| Aplastic anaemia | 2 | |
| Leukaemia | 1 | |
| Neuropathy | 1 | |
| Convulsion | 1 | |
| Headache | 1 | |
| Migraine | 1 | |
| Optic neuritis | 6 | |
| Visual disturbance | 5 | |
| Scotoma | 1 | |
| Nerve deafness | 2 | |
| Labyrinthitis | 1 | |
| Coronary occlusion | 1 | 1 |
| Jaundice | - 8 | 4 |
| Abnormal liver function tests | 2 | |
| Renal failure | 2 | 1 |
| Uraemia | 7 | |
| Albuminuria | 1 | |
| Frequency | 1 | |
| Polyuria | 1 | |
| Skin reactions | 5 | |
| Congenital abnormality | 1 | |
| | | |

| Prescriptions | (EC 10) | for | 1968 | 3,000 |
|---------------|---------|-----|------|--------|
| 11 | Ħ | 11 | 1969 | 14,000 |
| 11 | 11 | н | 1970 | 19,000 |

Pyrazinamian (71105)

'Zinamide'

Total reports July 1964-October 1971 25 (6 fatal) Reports not listed 1

| | Total | Deaths |
|-------------------------------|-------|--------|
| Hyperglycaemia | 1 | |
| Gout | 3 | |
| Coagulation defect | 1 | |
| Headache | 1 | |
| Visual disturbance | 3 | |
| Jaundice | 9 | 5 |
| Abnormal liver function tests | 2 | |
| Gastro-intestinal haemorrhage | 1 | 1 |
| Nausea and vomiting | 1 | |
| Albuminuria | 1 | |
| Skin reaction | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 7,000 |
|---------------|---------|-----|------|-------|
| 11 | н | 11 | 1969 | 7,000 |
| н | 18 | 11 | 1970 | 6,000 |

Prothionamide (71109)

'Trevintix'

Total reports March 1965-October 1971 16 (1 fatal) Reports not listed 2

| | Total | Deaths |
|-------------------------------|-------|--------|
| Gynaecomastia (male) | 1 | |
| Psychosis | 1 | |
| Jaundice | 2 | 1 |
| Abnormal liver function tests | 9 | |
| Albuminuria | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 6,000 |
|---------------|---------|-----|------|-------|
| 11 | н | 11 | 1969 | 4,000 |
| 11 | 11 | ti | 1970 | 2,000 |

Isoniazid (71110)

Alone or with drugs other than P A S

'B-Pasinah', 'Nicetal', 'Pycazide', 'Rimifon', 'Tebafen'
'Therazid', 'Therazid Forte', 'Thiazina', 'Trescazide'

Total reports May 1964-October 1971 65 (6 fatal) Reports not listed 5 (4 fatal)

| | Total | Deaths |
|-------------------------------|-------|--------|
| Gynaecomastia (male) | 1 | |
| Neutropenia | 2 | |
| Haemolytic anaemia | 1 | |
| Aplastic anaemia | 1 | 1 . |
| Hypochromic anaemia | 1 | |
| Schizophrenia | 2 | |
| Convulsion | 1 | |
| Syncope | 1 | |
| Somnolence | 1 | |
| Visual disturbance | 3 | |
| Scotoma | 1 | |
| Nerve deafness | 2 | |
| Jaundice | 10 | |
| Abnormal liver function tests | 11 | |
| Peptic ulcer | 1 | 1 |
| Gastritis | 1 | |
| Nausea and vomiting | 2 | |
| Uraemia | 1 | |
| Albuminuria | 1 | |
| Purpura | 1 | |
| Erythema multiforme | 1, | |
| Exfoliative dermatitis | 2 | |
| Alopecia | 1 | |
| Other skin reactions | 9 | |
| Congenital abnormality | 1 | |
| Pyrexia | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 35,000 |
|---------------|---------|-----|------|--------|
| 11 | | | 1969 | 44,000 |
| 18 | н | H | 1970 | 43,000 |

Isoniazid (71110) with P A S

'Dantyl-Inah', 'Inapasade', 'Pasinah', 'Pycamisan', 'Pycasix', 'Nisapas'

Total reports May 1964-October 1971 83 (14 fatal) Reports not listed 4

| | Total | Deaths |
|-------------------------------|-------|--------|
| Hypothyroidism | 1 | |
| Gout | 1 | |
| Avitaminosis | 1 | |
| Thrombocytopenia | 1 | |
| Leucopenia | 2 | |
| Haemolytic anaemia | 1 | |
| Aplastic anaemia | 3 | |
| Hypoplastic anaemia | 1 | |
| Macrocytic anaemia | 1 | |
| Psychosis | 1 | |
| Hallucinations | 1 | |
| Mental disorder | 1 | |
| Paralysis | 2 | |
| Cerebrovascular disorders | 1 | |
| Subarachnoid haemorrhage | 1 | 1 |
| Gait disorder | 1 | |
| Paraesthesia | 1 | |
| Spasticity | 1 | |
| Visual disturbance | 1 | |
| Vertigo | 1 | |
| Hypertension | 1 | |
| Venous thrombosis | | |
| site not stated | 1 | |
| Thrombophlebitis | 1 | |
| Jaundice | 30 | 11 |
| Abnormal liver function tests | 1 | |
| Steatorrhoea | 1 | |
| Gastro-intestinal haemorrhage | 1 | |
| Nausea and vomiting | 1 | 1 |
| Abdominal pain | 1 | |
| Nephropathy | 1 | |
| Renal failure | 2 | 1 |
| Exfoliative dermatitis | 1 | |
| Lupoid reaction | 2 | |
| Photosensitivity | 1 | |
| Other skin reactions | 5 | |
| Congenital abnormalities | 3 | |
| Arthralgia | 1 | |
| Pyrexia | 1 | |
| | | |

| Prescriptions | (EC 10) | for | 1968 | 120,000 |
|---------------|---------|-----|------|---------|
| п | Я | n | 1969 | 93,000 |
| 11 | 17 | 10 | 1970 | 61.000 |

Sodium Aminosalicylate (71120)

'Aminacyl Sodium', 'Bactylan', 'Dantyl', 'Paramisan', 'Pasade'

:otal reports June 1964-October 1971 98 (16 fatal) Reports not listed 11

| | Total | Deaths |
|-------------------------------|-------|--------|
| Hypothyroidism | 1 | |
| Gout | ī | |
| Oedema | 1 | |
| Avitaminosis | 1 | |
| Thrombocytopenia | 2 | |
| Leucopenia | 1 | |
| Haemolytic anaemia | 1 | |
| Aplastic anaemia | 4 | 1 |
| Macrocytic anaemia | 1 | |
| Hypoplastic anaemia | 1 | |
| Psychosis | 1 | |
| Hallucinations | 1 | |
| Mental disorder | 1 | |
| Paralysis | 1 | |
| Subarachnoid haemorrhage | 1 | 1 |
| Gait disorder | 1 | |
| Spasticity | 1 | |
| Visual disturbance | 2 | |
| Vertigo | 1 | |
| Hypertension | 1 | |
| Venous thrombosis | | |
| site not stated | 1 | |
| Thrombophlebitis | 1 | |
| Jaundice | 29 | 12 |
| Abnormal liver function tests | 1 | |
| Steatorrhoea | 1 | |
| Gastro-intestinal haemorrhage | 1 | |
| Diarrhoea | 1 | |
| Nausea and vomiting | 1 | 1 |
| Abdominal pain | 1 | |
| Nephropathy | 1 | |
| Renal failure | 2 | 1 |
| Uraemia | 5 | |
| Albuminuria | 1 | |
| Exfoliative dermatitis | 1 | |
| Lupoid reaction | 2 | |
| Photosensitivity | 1 | |
| Other skin reactions | 7 | |
| Congenital abnormalities | 3 | |
| Arthralgia | 1 | |
| Pyrexia | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 116,000 |
|---------------|---------|-----|------|---------|
| н | 11 | 11 | 1969 | 99,000 |
| 11 | 11 | 11 | 1970 | 88,000 |

Calcium Benzamidosalicylate (71125)

'B-Pasinah', 'Calcium B-PAS', 'Therapas', 'Therazid'

Total reports June 1967-October 1971 1
Reports not listed Nil

Total Deaths

Renal failure 1

| Prescriptions | (EC 10) | for | 1968 | 11,000 |
|---------------|---------|-----|------|--------|
| | ii | 11 | 1969 | 8,000 |
| п | н | 11 | 1970 | 5,000 |

Thiacetazone (71199)

'Berculon A', 'Thioparamizone'

Total reports May 1964-October 1971 16

Reports not listed Nil

| | Total | Deaths |
|-------------------------------|-------|--------|
| Leucopenia | 1 | |
| Neutropenia | 1 | |
| Haemolytic anaemia | 2 | |
| Aplastic anaemia | 1 | |
| Hypochromic anaemia | 1 | |
| Psychosis | 1 | |
| Somnolence | 1 | |
| Labyrinthitis | 1 | |
| Abnormal liver function tests | 4 | |
| Renal failure | 1 | |
| Skin reaction | 1 | |
| Congenital abnormality | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 2,000 |
|---------------|---------|-----|------|-------|
| Ħ | Ħ | 11 | 1969 | 1,000 |
| 11 | н | n | 1970 | 1,000 |

Dapsone (71202)

'Avlosulfon'

Total reports March 1965-October 1971 16 (2 fatal) Reports not listed 1

| | Total | Deaths |
|----------------------|-------|--------|
| Agranulocytosis | 2 | 1 |
| Haemolytic anaemia | 3 | |
| Methaemoglobinaemia | 1 | |
| Sulphaemoglobinaemia | 1 | |
| Leukaemia | 1 | 1 |
| Neuritis | 1 | |
| Visual disturbance | 1 | |
| Jaundice | 2 | |
| Diarrhoea | 1 | |
| Skin reactions | 2 | |

| Prescriptions | (EC 10) | for | 1968 | 11,000 |
|---------------|---------|-----|------|--------|
| II II | H | п | 1969 | 11,000 |
| 11 | 1) | 11 | 1970 | 11,000 |

Hexamine (71901)

'G 500', 'Mandelamine', 'Mandurin'

Total reports May 1966-October 1971 2 Reports not listed Nil

| | Total | Deaths |
|---------------------|-------|--------|
| Fluid retention | 1 | |
| Hypochromic anaemia | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 89,000 |
|---------------|---------|-----|------|--------|
| H | 11 | u | 1969 | 75,000 |
| . 11 | 19 | 10 | 1970 | 12,000 |

Phenazopyridine Hydrochloride (71902)

'Pyridium', 'Uromide'

Total reports August 1967-October 1971 7 Reports not listed Nil

| | Total | Deaths |
|---------------------|-------|--------|
| Haemolytic anaemia | 2 | |
| Paraesthesia | 1 | |
| Cyanosis | 1 | |
| Nausea and vomiting | 1 | |
| Skin reaction | 1 | |
| Arthralgia | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 28,000 |
|---------------|---------|-----|------|--------|
| 11 | | 11 | 1969 | 24,000 |
| 11 | 11 | н | 1970 | 23,000 |

Nitrofurantoin (71910)

'Berkfurin', 'Furadantin', 'Furan', 'N-Fur'

| Total reports April 1964-October Reports not li | | 306 (3 fatal) 13 (1 fatal) | | n 12 |
|---|----------|-------------------------------|-------|--------|
| | Total De | | Total | Deaths |
| Dedema | 1 | Dyspnoea | 14 | |
| Eosinophilia | 3 | Asthma | 2 | |
| Thrombocytopenia | 1 | Respiratory symptoms | 1 | |
| Leucopenia | 1 | Jaundice | 12 | 2 |
| Agranulocytosis | 2 | Gastritis | 1 | |
| Neutropenia | 1 | Salivary gland swelling | 1 | |
| Pancytopenia | 1 | Diarrhoea | 2 | |
| Haemolytic anaemia | 2 | Drymouth | | |
| Psychosis | 1 | Nausea and vomiting | | |
| Schizophrenia | 1 | Abdominal pain | 2 | |
| Depression | 4 | Anorexia | 2 | |
| Confusional state | 1 | Frequency | 1 | |
| Neuropathy | 13 | Urticaria | 29 | |
| Neuritis | 15 | Angioneurotic oedema | | |
| Syncope | 6 | Purpura | 8 | |
| Headache | 4 | Morbilliform rash | 2 | |
| Flushing | 1 | Scarlatiniform rash | 3 | |
| Generalised weakness | 1 | Erythema multiforme | _ | |
| Paraesthesia | 4 | Exfoliative dermatitis | | |
| Giddiness | 1 | Photosensitivity | 1 | |
| Retinitis | 1 | Eczema | | |
| Visual disturbance | .4 | Pemphigoid | | |
| Diplopia | 2 | Pigment change | | |
| Nerve deafness | 1 | Psoriasis | | |
| Vertigo | 2 | Pruritus | | |
| Hypotension | 3 | Other skin reactions | | |
| Tachycardia | 1 | Congenital abnormalities | | |
| Arrhythmia | 1 | Foetal distress | _ | |
| Angina | 1 | Anaphylaxis | | |
| Coronary occlusion | 1 | Rigor | | |
| Heart failure | 1 | Arthralgia | | |
| Chest pain | 2 | | | |
| Bronchospasm | 5 | Pyrexia | . 10 | |

| Prescriptions | (EC 10) | for | 1968 | 673,000 |
|---------------|---------|-----|------|---------|
| 11 | n | 19 | 1969 | 521,000 |
| 10 | 11 | 11 | 1970 | 488,000 |

Nalidixic Acid (71915)

'Negram'

Total reports June 1964-October 1971 700 (5 fatal) Reports not listed 31 (1 fatal)

| | Total | Deaths | | Total | Deaths |
|----------------------------|--------|--------|--------------------------|-------|--------|
| | , | | Superficial venous | | |
| Gout | 1 6 | | thrombosis | 1 | |
| Oedema | | | Cyanosis | 1 | |
| Acidosis | 2 | | Palpitations | 2 | |
| Eosinophilia | 1 2 | | Tachycardia | 2 | |
| Thrombocytopenia | 1 | | Angina | 1 | |
| Pancytopenia | 2 | | Oedema of upper | | |
| Haemolytic anaemia | | | respiratory tract | 1 | |
| Lymphadenopathy | 1 | | Dyspnoea | 1 | |
| Psychosis | 2 | | Sneezing | 1 | |
| Schizophrenia | 1 | | Pharyngitis | 1 | |
| Mania | 2 | | Jaundice | 6 | 1 |
| Depression | 1 | | Stomatitis | . 1 | |
| Confusional state | 3 | | Glossitis | 1 | |
| Delirium | 1 | | Gastro-intestinal | | |
| Hallucinations | 6 | | haemorrhage | 2 | |
| Emotional change | 1 | | Diarrhoea | 3 | |
| Mental disorder | 4 | | Nausea and vomiting | 23 | |
| Debility | 1 | | | 1 | |
| Reduced libido | 1 | | Abdominal pain | 2 | |
| Encephalitis | 1 | | Haematuria | | |
| Neuritis | 1 | 1 | Urticaria | 38 | |
| Convulsion | 6 | 1 | Angioneurotic oedema | 4 | |
| Coma | 3 | 1 | Purpura | 5 | |
| Syncope | 11 | | Morbilliform rash | 9 | |
| Somnolence | 5 | | Scarlatiniform rash | 2 | |
| Cerebral oedema | 5 | | Bullous eruption | 2 | |
| Headache | | | Erythema multiforme | 1 | |
| Photophobia | 13 | | Exfoliative dermatitis | 4 | 1 |
| Migraine | 1 | | Lupoid reaction | 1 | |
| Generalised weakness | 3 | | Photosensitivity | 41 | ~ |
| Disorder of sense of smell | 1 | | Eczema | 1 | |
| Gait disorder | 1 | | Epidermal necrolysis | 1 | |
| Tremor | 3 | | Alopecia | 2 | |
| Paraesthesia | 3 | | Pruritus | 1 | |
| Sensory disturbance | 3 | | Acne | 1 | |
| EEG abnormality | 1 | | Other skin reactions | 67 | |
| Abnormal movements | 2 | | Congenital abnormalities | 1 | |
| Giddiness | 26 | | Neonatal jaundice | 1 | |
| Optic neuritis | 2 | | Anaphylactic shock | 3 | |
| Papilloedema | 1 | | Anaphylaxis | 2 | |
| Visual disturbance | 262 | | Joint symptoms | 1 | |
| Diplopia | 2 | | Arthralgia | 3 | |
| Strabismus | 3 | | Muscle pain | 1 | |
| Hemianopia | 1 | | Tendinitis | 1 | |
| Colour blindness | 3 | | CSF pressure raised | 2 | |
| Nerve deafness | 1 | | Overdose | 1' | |
| Vertigo | 1 | | | | |
| Hypotension | 5 | | | | |

| Prescriptions | (EC 10) | for | 1968 | 407,000 |
|---------------|---------|-----|------|---------|
| H | п | 11 | 1969 | 349,000 |
| 1) | 11 | 18 | 1970 | 424,000 |

Quinine (72001)

'Anadin', 'Caapi', 'Fluscorbin'

Total reports March 1965-October 1971 27 (2 fatal) Reports not listed 13 (2 fatal)

| | Total | Deaths |
|-------------------------------|-------|--------|
| Thrombocytopenia | 2 | |
| Agranulocytosis | 1 | |
| Haemolytic anaemia | 1 | |
| Macrocytic anaemia | 1 | |
| Depression | 1 | |
| Confusional state | 1 | |
| Conjunctivitis | 1 | |
| Vasculitis | 1 | |
| Gastro-intestinal haemorrhage | 1 | |
| Skin reactions | 4 | |

| Prescriptions | (EC 10) | for | 1968 | 274,000 |
|---------------|---------|-----|------|---------|
| н | 11 | 11 | 1969 | 264;000 |
| II II | H | Ħ | 1970 | 313,000 |

Proguanil (72005)

'Paludrine'

Total reports August 1964-October 1971 2 Reports not listed Nil

| | Total | Deaths |
|----------|-------|--------|
| Jaundice | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 2,000 |
|---------------|---------|-----|------|-------|
| н | 11 | н | 1969 | 4,000 |
|)I | 11 | 11 | 1970 | 5,000 |

Pyrimethamine (72007)

'Daraclor' 'Daraprim'

Total reports December 1965-October 1971 7 Reports not listed Nil

| | Total | Deaths |
|--------------------|-------|--------|
| Thrombocytopenia | e e 3 | |
| Leucopenia | 1 | |
| Pancytopenia | 1 | |
| Aplastic anaemia | 1 | |
| Macrocytic anaemia | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 8,000 |
|---------------|---------|-----|------|-------|
| 11 | H | н | 1969 | 2,000 |
| н | 19 | н | 1970 | 300 |

Chloroquine (72020)

'Avloclor', 'Daraclor', 'Elestol', 'Lapaquin', 'Nivaquine', 'Nivembin', 'Resochin'

Total reports May 1964-October 1971 23
Reports not listed 2

| | Total | Deaths |
|-------------------------------|-------|--------|
| Pancytopenia | 1 | |
| Somnolence | 1 | |
| Generalised weakness | 1 | |
| Abnormal movements | 1 | |
| Retinitis | 8 | |
| Visual disturbance | 1 | |
| Diplopia | 1 | |
| Abnormal liver function tests | 1 | |
| Stomatitis | 1 | |
| Skin reactions | 4 | |
| Congenital abnormality | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 46,000 |
|---------------|---------|-----|------|--------|
| 11 | 11 | Ħ | 1969 | 43,000 |
| 10 | H | 11 | 1970 | 43,000 |

Hydroxychloroquine (72021)

'Plaquenil'

Total reports June 1964-October 1971 17 (4 fatal) Reports not listed 3

| | Total | Deaths |
|----------------------|-------|--------|
| Thrombocytopenia | 1 | |
| Leucopenia | 1 | |
| Neutropenia | 1 | |
| Aplastic anaemia | 2 | 2 |
| Neuropathy | 1 | |
| Syncope | 1 | |
| Jaundice | 1 | 1 |
| Nausea and vomiting | 1 | |
| Polyuria | 1 | |
| Skin reactions | 3 | |
| Periarteritis nodosa | 1 | 1 |

| Prescriptions | (EC 10) | for | 1968 | 40,000 |
|---------------|---------|-----|------|--------|
| 11 | 11 | 11 | 1969 | 44,000 |
| 11 | 11 | 11 | 1970 | 32,000 |

Mepacrine (72030)

Total reports September 1965-October 1971 2

Reports not listed 1

Clioquinol (72101)

(Present in a number of preparations available on free-sale in chemists shops)

Cotal reports February 1965-October 1971 26 Reports not listed 2

| | Total | Deaths |
|-------------------------|-------|--------|
| Oedema | 1 | |
| Thrombocytopenia | 1 | |
| Neuropathy | 3 | |
| Convulsion | 1 | |
| Sensory disturbance | 1 | |
| Angioneurotic oedema | 1 | |
| Photosensitivity | 2 | |
| Eczema | 2 | |
| Contact dermatitis | 1 | |
| Contact photodermatitis | 1 | |
| Necrosis of skin | 1 | |
| Hair colour change | 1 | |
| Other skin reactions | 7 | |
| Congenital abnormality | í | |

| Prescriptions | (EC 10) | for | 1968 | 495,000 |
|---------------|---------|-----|------|---------|
| 11 | и | | | 555,000 |
| H H | н | 19 | 1970 | 930,000 |

540

ANTHELMINTICS, ANTI-PROTOZOAL AND ANTI-FUNGAL AGENTS

Emetine (72110)

| Total reports May | y 1964-October 1971 | 1 (1 fatal) |
|-------------------|---------------------|-------------|
| | Reports not listed | Nil |

Total Deaths
Myocarditis 1 1

Acetarsol (72125)

'Stovarsol', 'SVC'

Total reports July 1967-October 1971 2 Reports not listed Nil

| | Total | Deaths |
|---------------|-------|--------|
| Jaundice | 1 | |
| Skin reaction | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 66,000 |
|---------------|---------|-----|------|--------|
| tt | Ħ | 11 | 1969 | 40,000 |
| 11 | 11 | 11 | 1970 | 39,000 |

Pentamidine Isethionate (72210)

Total reports August 1964-October 1971 3 Reports not listed Nil

| | Total | Deaths |
|--------------------------|-------|--------|
| Syncope | 2 | |
| Shock (not anaphylactic) | 1 | |

Furazolidone (72305)

'Furoxone'

Total reports July 1964-October 1971 11 Reports not listed 1

| | Total | Deaths |
|------------------------|-------|--------|
| Respiratory symptoms | 1 | |
| Albuminuria | 2 | |
| Skin reactions | 3 | |
| Reaction after alcohol | 4 | |

| Prescriptions | (EC 10) | for | 1968 | 79,000 |
|---------------|---------|-----|------|--------|
| 11 | 11 | 11 | 1969 | 76,000 |
| 11 | 11 | 11 | 1970 | 39,000 |

Metronidazole (72310)

'Flagyl'

Total reports June 1964-October 1971 125 Reports not listed 5

| | Total | Deaths |
|-------------------------------|---------|--------|
| Menstrual irregularities | 1 | |
| Diabetes mellitus | 1 | |
| Aplastic anemia | 1 | |
| Coagulation defect | 1 | |
| Leukaemia | 1 | |
| Depression | 5 | |
| Emotional change | 1 | |
| Mental disorder | 2 | |
| Neuropathy | 1 | |
| Neuritis | -1 | |
| Convulsion | 1 | |
| Coma | 1 | |
| Syncope | 2 | |
| Somnolence | 2 | |
| Headache | 7 | |
| Gait disorder | 2 | |
| Tremor | - 1 | |
| Paraesthesia | 1 | |
| Sleep disorder | 2 | |
| Giddiness | 4 | |
| Diplopia | 2 | |
| Vertigo | 3 | |
| Palpitations | 1 | |
| Dyspnoea | 2 | |
| Gastritis | 1 | |
| Glossitis | 7 | |
| Gastro-intestinal haemorrhage | 3 | |
| | 2 | |
| Diarrhoea | 13 | |
| Nausea and vomiting | 2 | |
| | 1 | |
| Haematuria | 2 | |
| Abortion | 18 | |
| Urticaria | 10 | |
| Angioneurotic oedema | 2 | |
| Purpura | 2 | |
| Morbilliform rash | 1 | |
| Pruritus | | |
| Other skin reactions | 13 4 | |
| Congenital abnormalities | 1 | |
| Anaphylaxis | _ | |
| Arthralgia | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 445,000 |
|---------------|---------|-----|------|---------|
| 11 | Ħ | 11 | 1969 | 433,000 |
| ti . | 11 | 11 | 1970 | 499,000 |

Nifuratel (72320)

'Magmilor'

Total reports October 1968-October 1971 27
Reports not listed 3

| | Total | Deaths |
|-------------------------|-------|--------|
| Oedema | 1 | |
| Mental disorder | 1 | |
| Convulsions | e 1 | |
| Somnolence | 1 | |
| Visual disturbance | 1 | |
| Vertigo | 1 | |
| Dyspnoea | 1 | |
| Nausea and vomiting | 2 | |
| Urticaria | 4 | |
| Angioneurotic oedema | 1 | |
| Morbilliform rash | 1 | |
| Localised skin reaction | 1 | |
| Pruritus | 1 | |
| Skin reactions | 3 | |
| Congenital abnormality | 1 | |
| Arthralgia | 2 | |
| Reaction after alcohol | 1 | |
| | | |

| Prescriptions | (EC 10) | for | 1968 | 19,000 |
|---------------|---------|-----|------|--------|
| п | | 1) | 1969 | 65,000 |
| 11 | 11 | 11 | 1970 | 48,000 |

Cloponone (72401)

'Ginetris'

Total reports February 1969-October 1971 3 Reports not listed Nil

| | Total | Deaths |
|----------------|-------|--------|
| Vaginitis | 1 | |
| Skin reactions | 2 | |

| Prescriptions | (EC 10) | for | 1968 | 43,000 |
|---------------|---------|-----|------|--------|
| 11 | н | H | 1969 | 42,000 |
| 11 | H | n | 1970 | 22,000 |

Myralact (72451)

'Ginetris'

Total reports May 1968-October 1971 3 Reports not listed Nil

| | Total | Deaths |
|---------------|-------|--------|
| Vaginitis | 1 | |
| Skin reaction | 2 | |

| Prescriptions | (EC 10) | for | 1968 | 43,000 |
|---------------|---------|-----|------|--------|
| H | Ħ | 11 | 1969 | 42,000 |
| н | II | 11 | 1970 | 22,000 |

Piperazine (73005)

'Antepar', 'Entacyl', 'Pipergran', 'Pripsen'

Total reports May 1964-October 1971 34 (1 fatal) Reports not listed Nil

| | Total | Deaths |
|-------------------------------|-------|--------|
| Oedema | 1 | |
| Tetany | 1 | |
| Hypochromic anaemia | 1 | |
| Confusional state | 1 | |
| Hallucinations | 1 | |
| Emotional change | 1 | |
| Encephalitis | 1 | 1 |
| Convulsion | | |
| Somnolence | 1 | |
| Generalised weakness | 1 | |
| Gait disorder | 8 | |
| Giddiness | 2 | |
| Visual disturbance | 2 | |
| Shock (non anaphylactic) | 1 | |
| Dyspnoea | 1 | |
| Gastro-intestinal haemorrhage | 1 | |
| Nausea and vomiting | 1 | |
| Urticaria | 2 | |
| Erythema multiforme | 1 | |
| Skin reactions | 4 | |
| Overdose | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 268,000 |
|---------------|---------|-----|------|---------|
| 11 | 11 | 11 | 1969 | 276,000 |
| В | 17 | 17 | 1970 | 250,000 |

Dichlorophen (73012)

'Anthiphen'

Total reports September 1967-October 1971 1

Reports not listed Nil

| Prescriptions | (EC 10) | for | 1968 | 1,000 |
|---------------|---------|-----|------|-------|
| 11 | 11 | 19 | 1969 | 1,000 |
| 17 | 17 | #1 | 1970 | 3,000 |

Thiabendazole (73015)

'Mintezol'

Total reports April 1967-October 1971 14 (1 fatal) Reports not listed Nil

| | Total | Deaths |
|----------------|-------|--------|
| Psychosis | 1 | |
| Hallucinations | 2 | |
| Debility | 2 | |
| Convulsions | 3 | |
| Cardiac arrest | 1 | 1 |
| Jaundice | 1 | |
| Anorexia | 1 | |
| Skin reaction | .1 | |
| fuscle pain | 2 | |
| | | |

Nystatin (74002)

'Lederstatin', 'Mysteclin', 'Nystan', 'Nystaform HC'
'Nystaform', 'Tri-Adcortyl Cream'

Total reports June 1964-October 1971 52 (4 fatal)

Reports not listed 9 (3 fatal)

| | Total | Deaths |
|------------------------|-------|--------|
| Oedema | 1 | |
| Leucopenia | 1 | |
| Delirium | 1 | |
| Heada c he | 5 | |
| Amblyopia | 1 | |
| Vertigo | 1 | |
| Pharyngitis | 1 | |
| Jaundice | 1 | |
| Colitis | 1 | 1 |
| Constipation | 1 | |
| Diarrhoea | 2 | |
| Abdominal pain | 1 | |
| Vaginitis | 1 | |
| Urticaria | 5 | |
| Purpura | 1 | |
| Morbilliform rash | 1 | |
| Erythema multiforme | 1 | |
| Contact dermatitis | 3 | |
| Other skin reactions | 11 | |
| Congenital abnormality | 2 | |
| Rigor | 1 | |
| | | |

| Prescriptions | (EC 10) | for | 1968 | 1,942,000 |
|---------------|---------|-----|------|-----------|
| п | 1) | H | 1969 | 1,788,000 |
| 11 | н | Ħ | 1970 | 2.101.000 |

Griseofulvin (74006)

'Fulcin', 'Grisovin'

Total reports May 1964-October 1971 54 Reports not listed 2

| | Total | Deaths |
|--------------------------|-------|--------|
| Menstrual irregularities | 1 | |
| Weight loss | 1 | |
| Gout | 1 | |
| Thrombocytopenia | 1 | |
| Impotence | 1 | |
| Somnolence | 1 | |
| Headache | 5 | |
| Migraine | 1 | |
| Paraesthesia | 1 | |
| Strabismus | 1 | |
| Vasculitis | 1 | |
| Jaundice | 1 | |
| Glossitis | 1 | |
| Nausea and vomiting | 1 | |
| Abdominal pain | 1 | |
| Albuminuria | 2 | |
| Dysuria | 1 | |
| Urticaria | 7 | |
| Morbilliform rash | 1 | |
| Erythema multiforme | . 2 | |
| Photosensitivity | 1 | |
| Alopecia | 1 | |
| Pruritus | 1 | |
| Other skin reactions | 15 | |
| Congenital abnormalities | 2 | |

| Prescriptions | (EC 10) | for | 1968 | 94,000 |
|---------------|---------|-----|------|---------|
| 89 | н | 11 | 1969 | 99,000 |
| 11 | 17 | 11 | 1970 | 110,000 |

Amphotericin B (74008)

'Fungilin', 'Fungizone'

Total reports June 1964-October 1971 17 (1 fatal)
Reports not listed 4 (1 fatal)

| | Total | Deaths |
|-------------------------|-------|--------|
| Thrombocytopenia | 1 | |
| Headache | 1 | |
| Visual disturbance | 2 | |
| Urticaria | 1 | |
| Purpura | 1 | |
| Morbilliform rash | 1 | |
| Localised skin reaction | 1 | |
| Other skin reactions | 3 | |
| Congenital abnormality | 1 | |
| Anaphylactic shock | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 485,000 |
|---------------|---------|-----|------|---------|
| 11 | н | 11 | 1969 | 398,000 |
| H | 11 | 11 | 1970 | 435,000 |

Pecilocin (74010)

'Variotin'

Total reports April 1965-October 1971 7 Reports not listed Nil

| | Total | Deaths |
|-------------------------|-------|--------|
| Eczema | 3 | |
| Contact dermatitis | 1 | |
| Localised skin reaction | 1 | |
| Other skin reactions | 2 | |

| Prescriptions | (EC 10) | for | 1968 | 19,000 |
|---------------|---------|-----|------|--------|
| 11 | 17 | 11 | 1969 | 26,000 |
| Ħ | 10 | 11 | 1970 | 18.000 |

Undecenoic Acid (74105)

'Ceanal', 'Monphytol', 'Mycota', 'Quatrasol'

Total reports March 1967-October 1971 2

Reports not listed 1

Total Deaths

Skin reaction 1

Buclosamide (74110)

'Jadit'

Total reports October 1965-October 1971 3
Reports not listed Nil

Total Deaths

Skin reactions 3

| Prescriptions | (EC 10) | for | 1968 | 28,000 |
|---------------|---------|-----|------|--------|
| 11 | 11 | 11 | 1969 | 29,000 |
| It | 19 | 11 | 1970 | 30,000 |

Tolnaftate (74201)

'Tinaderm'

Total reports February 1968-October 1971 4
Reports not listed Nil

| | Total | Deaths |
|----------------|-------|--------|
| Oedema | 1 | |
| Skin reactions | 3 | |

| Prescriptions | (EC 10) | for | 1968 | 115,000 |
|---------------|---------|-----|------|---------|
| H | 11 | 11 | 1969 | 129,000 |
| п | п | B | 1970 | 140,000 |

Chlorhexidine (76240)

'Hibitane', 'Naseptin', 'Novesine'

Total reports April 1965-October 1971 10 Reports not listed 1

| | Total | Deaths |
|---------------------------|-------|--------|
| Potentiation of infection | | |
| by adrenal steroids | 1 | |
| Urticaria | 1 | |
| Morbilliform rash | 1 | |
| Contact dermatitis | 2 | |
| Localised skin reactions | 2 | |
| Other skin reactions | 1 | |
| Slow healing | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 130,000 |
|---------------|---------|-----|------|---------|
| 11 | 11 | 18 | 1969 | 131,000 |
| н | 89 | 11 | 1970 | 261,000 |

Benzoyl Peroxide (76350)

'Quinoderm', 'Vanair'

Total reports November 1964-October 1971 5
Reports not listed Nil

Total Deaths

Skin reactions 5

| Prescriptions | (EC 10) | for | 1968 | 128,000 |
|---------------|---------|-----|------|---------|
| П | 11 | | 1969 | |
| 11 | 11 | 11 | 1970 | 222,000 |

Borax (76360)

Total reports December 1969-October 1971 2 Reports not listed Nil

| | Total | Deaths |
|---------------|-------|--------|
| Pharyngitis | 1 | |
| Skin reaction | 1 | |

Benzalkonium Chloride (76401)

Total reports March 1965-October 1971 20 Reports not listed 3

| | Total | Deaths |
|--------------------------|-------|--------|
| Syncope | 1 | |
| Conjunctivitis | 3 | |
| Vaginitis | 3 | |
| Urticaria | 2 | |
| Eczema | 3 | |
| Contact dermatitis | 1 | |
| Localised skin reactions | 3 | |
| Other skin reaction | 1 | |

Benzethonium (76403)

'Emko', 'Orthoforms'

Total reports March 1965-October 1971 5 Reports not listed Nil

| | Total | Deaths |
|---------------|-------|--------|
| Urethritis | 3 | |
| Dysuria | 1 | |
| Skin reaction | 1 | |

Cetrimide (76405)

'Cetavlon', 'Quatrasol'

Total reports January 1965-October 1971 19 (1 fatal) Reports not listed 2

| | Total | Deaths |
|--------------------------|-------|--------|
| Shock (non anaphylactic) | 1 | 1 |
| Urticaria | 1 | |
| Morbilliform rash | 1 | |
| Exfoliative dermatitis | 1 | |
| Eczema | 1 | |
| Contact dermatitis | 4 | |
| Localised skin reactions | 4 | |
| Other skin reactions | 3 | |
| Anaphylaxis | 1 | |

Cetylpyridinium (76407)

'Merocet', 'Toracsol'

Total reports June 1967-October 1971 5 Reports not listed Nil

| | Total | peaths |
|--------------------|-------|--------|
| Haemolytic anaemia | 1 | |
| Glossitis | 1 | |
| Skin reactions | 3 | |

Dequalinium Chloride (76450)

'Dequadin'

Total reports August 1964-October 1971 25
Reports not listed Nil

| | Total | Deaths |
|-------------------------|-------|--------|
| Hyperaesthesia | 1 | |
| Pharyngitis | 2 | |
| Dysuria | 1 | |
| Urticaria | 1 | |
| Morbilliform rash | 1 | |
| Necrosis of skin | | |
| (not from injection) | 14 | |
| Localised skin reaction | 1 | |
| Other skin reactions | 4 | |

| Prescriptions | (EC 10) | for | 1968 | 472,000 |
|---------------|---------|-----|------|---------|
| 11 | H | 17 | 1969 | 395,000 |
| н | tt . | 11 | 1970 | 347,000 |

Domiohen bromide (76451)

'Bradosol'

Total reports February 1965-October 1971 2 Reports not listed Nil

| | Total | Deaths |
|---------------|-------|--------|
| Pharyngitis | 1 | |
| Skin reaction | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 237,000 |
|---------------|---------|-----|------|---------|
| 11 | If | 11 | 1969 | 170,000 |
| 19 | 11 | 11 | 1970 | 159,000 |

Influenza virus vaccine (inactivated) (78001)

'Admune', 'Flugen', 'Flugen E', 'Influvac'

Total reports March 1964-Cctober 1971 105 (8 fatal) Reports not listed 5

| | Total | Deaths |
|--------------------------|-------|--------|
| Oedema | 2 | |
| Leucopenia | 1 | 1 |
| Aplastic anaemia | 1 | 1 |
| Encephalitis | 4 | |
| Neuropathy | 3 | 1 |
| Neuritis | 1 | |
| Convulsion | 1 | |
| Syncope | 1 | |
| Headache | 1 | |
| Abnormal taste | 2 | |
| Cardiac arrest | 1 | 1 |
| Pericarditis | 1 | |
| Coronary occlusion | 1 | |
| Heart failure | 1 | 1 |
| Chest pain | 1 | |
| Bronchospasm | 2 | |
| Dyspnoea | 1 | 1 |
| Cough | 1 | |
| Respiratory symptoms | 2 | 1 |
| Anuria | 1 | |
| Polyuria | 1 | |
| Urticaria | 5 | |
| Photosensitivity | 1 | |
| Oil Granuloma | 17 | |
| Localised skin reactions | 13 | |
| Granuloma | 3 | |
| Other skin reactions | 3 | |
| Congenital abnormality | 1 | |
| Anaphylactic shock | 3 | 1 |
| Pyrexia | 16 | |
| Muscle pain | 3 | |
| Inflammation following | | |
| subcutaneous injection | 5 | |

Poliomyelitis vaccine (inactivated) (78069)

'Polivirin'

Total reports May 1964-October 1971 18 (1 fatal) Reports not listed Nil

| | Total | Deaths |
|------------------------|-------|--------|
| Encephalitis | 1 | 1 |
| Convulsions | 1 | |
| EEG abnormality | 1 | |
| Stridor | 1 | |
| Cough | 1 | |
| Nausea and vomiting | 1 | |
| Skin reaction | 1 | |
| Anaphylactic shock | 1 | |
| Anaphylaxis | 5 | |
| Rigor | 2 | |
| Pyrexia | 1 | |
| Inflammation following | | |
| subcutaneous injection | 2 | |

Poliomyelitis vaccine (oral) (78070)

Total reports May 1964-October 1971 69 (3 fatal)
Reports not listed 12

| | Total | Deaths |
|--------------------------|-------|--------|
| Muscle weakness | 1 | |
| Oedema | 2 | |
| Debility | 1 | |
| Encephalitis | 6 | |
| Paralysis | 1 | |
| Convulsion | 12 | 1 |
| Syncope | 1 | |
| Somnolence | 1 | |
| Tremor | 1 | |
| Abnormal movements | 1 | |
| Optic neuritis | 1 | |
| Shock (not anaphylactic) | 1 | |
| Oedema of upper | | • |
| respiratory tract | 1 | |
| Respiratory symptoms | 2 | 2 |
| Diarrhoea | 1 | |
| Nausea and vomiting | 1 | |
| Urticaria | 4 | |
| Eczema | 1 | |
| Other skin reaction | 1 | |
| Congenital abnormalities | 2 | |
| Pyrexia | 13 | |
| Muscle pain | ĺ | |
| Pallor | 1 | |
| | | |

Measles virus vaccine (live attenuated) (78075)

'Mevilin-L', 'wellcovax'

| Total reports | May 1966-December 1969 | 544 (7 fatal) |
|---------------|------------------------|---------------|
| 10002 | Reports not listed | |

| and the same and the same | Total | Deaths | | Total | Deaths |
|---------------------------|-------|--------|------------------------------|-------|--------|
| Electrolyte abnormality | 1 | 1 | Haemoptysis | 2 | |
| Thrombocytopenia | 4 | | Respiratory symptoms | 28 | |
| Lymphadenopathy | 5 | | Jaundice | 4 | |
| Delirium | 2 | | Stomatitis | 1 | |
| Hallucinations | | | Diarrhoea | 4 | |
| Debility | . 4 | | Nausea and vomiting | 6 | |
| Encephalitis | O.A | 4 | Anorexia | 7 | |
| Neuritis | . 1 | | Urticaria | 5 | |
| Paralysis | . 1 | | Angioneurotic oedema | 1 | |
| Convulsion | 250 | | Purpura | 4 | |
| Coma | 0 | | Morbilliform rash | 37 | |
| Cerebral oedema | . 1 | 1 | Bullous eruption | 1 | |
| Headache | . 3 | | Stevens Johnson Syndrome | 1 | |
| Hyperpyrexia | . 5 | | Eczema | 1 | |
| Gait disorder | | | Psoriasis | 1 | |
| Stammer | 7 | | Anaphylactic shock | 1 | |
| Conjunctivitis | | | Anaphylaxis | 2 | |
| Strabismus | 0 | | Pyrexia | 80 | |
| Nerve deafness | . 1 | | Cross-infection | 1 | |
| Otitis media | . 3 | | Transmission of live | | |
| Bronchospasm | | | vaccine virus from immunised | | |
| Rhinitis | Α. | | person to another | . 1 | |
| Pharyngitis | 3 | | Persistent screaming | | |

Measles virus vaccine (inactivated) (78076)

'Mesavac'

Total reports October 1965-October 1971 3 Reports not listed Nil

| | Total | Deaths |
|-------------|-------|--------|
| Convulsions | 1 | |
| Pyrexia | 1 | |

Yellow fever vaccine (78080)

Total reports July 1967-October 1971 5 (1 fatal) Reports not listed 1

| | Total | Deaths |
|--------------------|-------|--------|
| Haemolytic anaemia | 1 | 1 |
| Encephalitis | 1 | |
| Jaundice | 1 | |
| Pyrexia | 1 | |

Rubella vaccine (78090)

'Cendevax'

Total reports May 1971-October 1971 10 Reports not listed Nil

| | Total | Deaths |
|---------------------|-------|--------|
| Oedema | 1 | |
| Thrombocytopenia | 2 | |
| Encephalitis | 1 | |
| Paralysis | 1 | |
| Syncope | 1 | |
| Nausea and vomiting | 1 | |
| Skin reaction | 1 | |
| Anaphylaxis | 1 | |
| Arthralgia | 1 | |

Pertussis vaccine (78101)
Diphtheria vaccine (78201)
Tetanus vaccine (78210)

'Triple Antigen', 'Trivax'

Total reports May 1964-October 1971 425 (17 fatal)

| Reports not | liste | d | 2 | | |
|--------------------------|---------|--------|--------------------------|------|--------|
| | Total | Deaths | Т | otal | Deaths |
| Oedema | 2 | | Anorexia | 3 | |
| Emotional change | 29 | | Urticaria | 12 | |
| Debility | 10 | | Angioneurotic oedema | 1 | |
| Encephalitis | 10 | 3 | Purpura | 1 | |
| Convulsions | 33 | 3 | Morbilliform rash | 1 | |
| Grand Mal convulsion | 33 6 |) | Scarlatiniform rash | 1 | |
| Petit Mal convulsion | | | Eczema | 4 | |
| Coma | 1 | | Seborrhoea | 1 | |
| Syncope | 2 | - | Other skin reactions | 16 | |
| Sumnolence | 11 | 1 | Anaphylactic shock | 6 | 2 |
| Hyperpyrexia | 5 | | Anaphylaxis | 9 | 2 |
| Tremor | J. | 1 | | 5 | |
| | Τ. | | Rigor | | , |
| Sleep disorder | | | Pyrexia | | 1 |
| EEG abnormality | - | | Pallor | 2 | |
| Abnormal movements | | | Abscess following | _ | |
| Shock (not anaphylactic) | L. | | subcutaneous injection | 3 | |
| Cyanosis | 6 | | Inflammation following | | |
| Tachycardia | | | subcutaneous injection | 65 | |
| Stridor | 1 | | Swelling following | | |
| Apnoea | 1 | | subcutaneous injection | 24 | |
| Cough | | | Inflammation following | | |
| Asthma | | | intra-muscular injection | 4 | |
| Respiratory sysmptoms | | 4 | Swelling following | | |
| Diarrhoea | | 7 | intra-muscular injection | 1 | |
| Nausea and vomiting | | 2 | Persistent screaming | 12 | |
| | 17 | - 2 | | | |

Salmonella Typhi (78105)
Salmonella Paratyphi A (78106)
Salmonella Paratyphi B (78107)

'T.A.B.

Total reports October 1965-October 1971 15 (2 fatal) Reports not listed 1

| Thrombocytopenia | 1 | |
|------------------|---|---|
| Paralysis | 1 | |
| Hyperpyrexia | 2 | 2 |
| Apnoea | 1 | |
| Abdominal pain | 1 | |
| Renal failure | 1 | |
| Skin reaction | 2 | |
| Anaphylaxis | 1 | |
| Pyrexia | 3 | |
| Muscle pain | 1 | |

Cholera vaccine (78108)

Total reports February 1970-October 1971 5 Reports not listed 1

| | Total | Deaths |
|-------------------|-------|--------|
| Thrombocytopenia: | 1 | |
| Skin reaction | 1 | |
| Anaphylaxis | 1 | |
| Muscle pain | 1 | |

Bacillus Calmette-Guerin vaccine (78171)

'B.C.G.'

Total reports January 1966-October 1971 7 Reports not listed Nil

| | Total | Deaths |
|------------------------|-------|--------|
| Oedema | 2 | |
| Skin reaction | 1 | |
| Anaphylaxis | 2 | |
| Inflammation following | | |
| intra-dermal injection | 2 | |

Smallpox vaccine (78180)

Total reports July 1967-October 1971 48 (6 fatal) Reports not listed 3 (1 fatal)

| | Total | Deaths |
|------------------------|-------|--------|
| Encephalitis | 12 | 5 |
| Paralysis | 1 | |
| Convulsions | 5 | |
| Hyperpyrexia | 1 | |
| Generalised weakness | 1 | |
| Keratitis | 1 | |
| Vasculitis | 1 | |
| Erythema multiforme | 3 | |
| Vaccinia | 6 | |
| Eczema | 2 | |
| Other skin reactions | 8 | |
| Muscle pain | î | |
| Inflammation following | | |
| intra-dermal injection | 2 | |
| Swelling following | | |
| intra-dermal injection | 1 | |

Diphtheria vaccine (78201) with Tetanus vaccine (78210)

Total reports June 1964-October 1971 31 Reports not listed Nil

| | Total | Deaths |
|-------------------------|-------|--------|
| Oedema | 2 | |
| Confusional state | 1 | |
| Emotional change | 1 | |
| Convulsion | 2 | |
| Syncope | 1 | |
| Pharyngitis | 1 | |
| Diarrhoea | 1 | |
| Nausea and vomiting | 1 | |
| Urticaria | 3 | |
| Localised skin reaction | 4 | |
| Anaphylactic shock | 2 | |
| Anaphylaxis | 1 | |
| Inflammation following | 7 | |
| subcutaneous injection | 11 | |
| Subcubaneous Injection | 11 | |

Tetanus Vaccine (78210)

Total reports June 1964-October 1971 73 Reports not listed 11

| | Total | Deaths |
|----------------------------|-------|--------|
| Oedema | 2 | |
| Debility | 1 | |
| Convulsion | 1 | |
| Syncope | 1 | |
| Somnolence | 1 | |
| Headache | 1 | |
| Conjunctivitis | 1 | |
| Shock (not anaphylactic) | 2 | |
| Urticaria | 4 | |
| Localised skin reactions | 24 | |
| Other skin reactions | 5 | |
| Anaphylactic shock | - 1 | |
| Anaphylaxis | 2 | |
| Pyrexia | 1 | |
| Inflammation following | _ | |
| injection | 13 | |
| Oedema following injection | 2 | |

Tetanus Antitoxin (78510)

Total reports March 1964-October 1971 14 Reports not listed 1

| | Total | Deaths |
|---------------------------|-------|--------|
| Oedema | 1 | |
| Confusional state | 1 | |
| Cerebrovascular disorders | 1 | |
| Headache | 1 | |
| Urticaria | 2 | |
| Angioneurotic oedema | 1 | |
| Morbilliform rash | 1 | |
| Localised skin reach as | 2 | |
| Other skin reactions | 2 | |
| Pyrexia | 1 | |

Gamma Globulin (78950)

Total reports October 1966-October 1971 14 Reports not listed Nil

| To | otal Deaths |
|----------|------------------|
| Abortion | 5 5 1 1 |

Human Fibrinogen (78990)

Total reports November 1969-October 1971 2
Reports not listed Nil

Total Deaths

Jaundice 2

Diatrizoic Acid (90002)

'Gastrografin', 'Hypaque'

Total reports April 1964-October 1971 42 (3 fatal) Reports not listed Nil

| | Total | Deaths |
|--------------------------|-------|--------|
| Oedema | 2 | |
| Memory impairment | 1 | |
| Convulsions | 2 | |
| Syncope | 1 | |
| Hypotension | 3 | |
| Shock (not anaphylactic) | 2 | |
| Cardiac arrest | 1 | |
| Chest pain | 1 | |
| Bronchospasm | 1 | |
| Rhinitis | 1 | |
| Nausea and vomiting | 6 | |
| Urticaria | 7 | |
| Angioneurotic oedema | 4 | |
| Other skin reaction | 3 | |
| Anaphylactic shock | 7 | 3 |
| | | |

Sodium Metrizoate (90003)

'Triosil'

Total reports March 1964-October 1971 6 (2 fatal) Reports not listed 1 (1 fatal)

| | Total | Deaths |
|---------------------|-------|--------|
| Hypotension | 2 | 1 |
| Nausea and vomiting | 3 | |

Meglumine Diatrizoate (90006) with

Diatrizoic Acid (90002)

'Urografin', 'Urovision'

Total reports November 1964-October 1971 37 (5 fatal) Reports not listed Nil

| | Total | Deaths |
|--------------------------|-------|--------|
| Convulsion | 1 | |
| Syncope | 3 | |
| Hypotension | 3 | |
| Shock (not anaphylactic) | 2 | |
| Hypertension | 1 | |
| Cardiac arrest | 2 | 2 |
| Heart failure | 1 | 1 |
| Bronchospasm | 3 | |
| Diarrhoea | 1 | |
| Nausea and vomiting | 4 | |
| Urticaria | 4 | |
| Angioneurotic oedema | 2 | |
| Other skin reactions | 3 | |
| Anaphylactic shock | 3 | 1 |
| Anaphylaxis | 3 | |
| Overdose | 1 | 1 |

Sodium (and calcium) Ipodate (90007)

'Biloptin', 'Solu-Biloptin'

Total reports May 1964-October 1971 15 Reports not listed 2

| | Total | Deaths |
|----------------------------|--------|--------|
| Oedema Nausea and vomiting | 3 3 | |
| Skin reactions | 5 1 | |
| Anaphylaxis | 1 | |

Iopanoic Acid (90008)

'Telepaque'

Total reports November 1964-October 1971 5 (1 fatal) Reports not listed Nil

| | Total | Deaths |
|----------------|-------|--------|
| Oedema | 1 | |
| Syncope | 1 | |
| Renal failure | 1 | 1 |
| Skin reactions | 2 | |

Methylglucamine Iodipamide (90009)

'Biligrafin'

Total reports February 1965-December 1969 18 (3 fatal) Reports not listed 2

| | Total | Deaths |
|--------------------------|-------|--------|
| Syncope | 1 | |
| Hypotension | 2 | |
| Shock (not anaphylactic) | 1 | |
| Nausea and vomiting | 1 | |
| Renal failure | 3 | 1 |
| Skin reactions | 5 | |
| Anaphylactic shock | 2 | 1 |
| Anaphylaxis | 1 | 1 |

Sodium Iothalamate (90020) Meglumine Iothalamate (90021)

'Conray' (range)

Total reports February 1965-October 1971 18 (4 fatal) Reports not listed Nil

| | Total | Deaths |
|---------------------------|-------|--------|
| Oedema | 1 | |
| Coma | 1 | 1 |
| Syncope | 1 | |
| Cerebrovascular disorders | 1 | |
| Blindness | 1 | |
| Shock (not anaphylactic) | 3 | |
| Cardiac arrest | 1 | 1 |
| Bronchospasm | 1 | |
| Nausea and vomiting | 1 | |
| Renal failure | 1 | 1 |
| Skin reactions | 4 | |
| Anaphylaxis | 2 | 1 |

<u>Iodised 0il (90030)</u>

'Lipiodol'

Total reports July 1966-October 1971 6
Reports not listed Nil

Total Deaths
Haemoptysis 6

Dihydroxyphenylisatin (90031)

'Veripaque'

Total reports March 1964-October 1971 3 (1 fatal)

Reports not listed 2 (1 fatal)

MISCELLANEOUS DIAGNOSTIC AGENTS

Pentagastrin (90110)

'Peptavlon'

Total reports June 1967-October 1971 3 Reports not listed Nil

| | Total | Deaths |
|--------------------------|-------|--------|
| Shock (not anaphylactic) | 1 | |
| Nausea and vomiting | 2 | |

MISCELLANEOUS DIAGNOSTIC AGENTS

Sulphobromophthalein (90141)

Total reports August 1965-October 1971 7 Reports not listed Nil

| | Total | Deaths |
|----------------|-------|--------|
| Hypotension | 2 | |
| Cardiac arrest | 1 | |
| Skin reaction | 1 | |
| Anaphylaxis | 3 | |

Methotrexate (91005)

Total reports June 1964-October 1971 16 (6 fatal) Reports not listed 1

| | Total | Deaths |
|----------------------|-------|--------|
| Thrombocytopenia | 1 | 1 |
| Leucopenia | 2 | 1 |
| Agranulocytosis | 1 | 1 |
| Pancytopenia | 1 | 1 |
| Leukaemia | 1 | 1 |
| Neuropathy | 1 | |
| Paralysis | 2 | |
| Generalised weakness | 1 | |
| Paraesthesia | 1 | |
| Nausea and vomiting | 1 | 1 |
| Pyrexia | 1 | |
| Muscle pain | 1 | |
| Carcinoma | 1 | |

Azathioprine (91020)

(Imuran*

Total reports January 1966-October 1971 18 (5 fatal) Reports not listed 3 (1 fatal)

| | Total | Deaths |
|---------------------------|-------|--------|
| Potentiation of infection | | |
| by adrenal steroids | 1 | 1 |
| Oedema | 1 | |
| Thrombocytopenia | 1 | |
| Pancytopenia | 2 | 1 |
| Aplastic anaemia | 2 | 1 |
| Psychosis | 1 | |
| Generalised weakness | 1 | |
| Visual disturbance | 1 | |
| Heart failure | 1 | 1 |
| Jaundice | 1 | |
| Nausea and vomiting | 3 | |

Procarbazine (91090)

'Natulan'

Total reports February 1967-October 1971 5 (1 fatal) Reports not listed Nil

| | Total | Deaths |
|------------------------|-------|--------|
| Pancytopenia | 1 | |
| Hypoplastic anaemia | 1 | |
| Somnolence | 1 | |
| Hypotension (postural) | 1 | 1 |
| Skin reaction | 1 | |

Nitrogen mustard (91100)

Total reports Nay 1964-October 1971 3 (3 fatal) Reports not listed Nil

| | Total | Deaths |
|------------------------|-------|--------|
| Aplastic anaemia | 2 | 2 |
| Hypotension (postural) | 1 | 1 |

Busulphan (91101)

'Myleran'

Total reports August 1964-October 1971 8 (6 fatal) Reports not listed Nil

| | Total | Deaths |
|----------------------|-------|--------|
| Hypoadrenocorticism | 1 | 1 |
| Thrombocytopenia | 1 | 1 |
| Aplastic anaemia | 3 | 3 |
| Respiratory symptoms | 1 | |
| Jaundice | 1 | 1 |
| Skin reaction | 1 | |

Melphalan (91102)

'Alkeran'

Total reports May 1965-October 1971 6 (4 fatal) Reports not listed Nil

| | Total | Deaths |
|---------------------|-------|--------|
| Thrombocytopenia | 3 | 2 |
| Agranulocytosis | 1 | 1 |
| Pancytopenia | 1 | 1 |
| Nausea and vomiting | 1 | |

Chlorambucil (91103)

'Leukeran'

Total reports November 1967-October 1971 16 (3 fatal) Reports not listed 3

| | Total | Deaths |
|----------------------|-------|--------|
| Oedema | 1 | |
| Thrombocytopenia | 1 | |
| Agranulocytosis | 1 | 1 |
| Aplastic anaemia | 1 | 1 |
| Angioneurotic oedema | 1 | |
| Bullous eruption | 1 | |
| Alopecia | 1 | |
| Other skin reactions | 5 | |
| Sepsis | 1 | 1 |

Fluorouracil (91104)

Total reports November 1967-October 1971 2
Reports not listed 1

Total Deaths

Visual disturbance • • • • 1

Cyclophosphamide (91105)

'Endoxana'

Total reports June 1964-October 1971 33 (6 fatal) Reports not listed Nil

| | Total | Deaths |
|---------------------------|-------|--------|
| Potentiation of infection | | |
| by adrenal steroids | 1 | |
| Diabetes mellitus | 3 | |
| Thrombocytopenia | 3 | 2 |
| Leucopenia | | 1 |
| Agranulocytosis | 2 | 2 |
| Neutropenia | | |
| Aplastic anaemia | 3 | 1 |
| Confusional state | 1 | |
| Neuropathy | 1 | |
| Convulsion | 1 | |
| Syncope | | |
| Nausea and vomiting | | |
| Albuminuria | 2 | |
| Haematuria | 2 | |
| Cystitis | 1 | |
| Nocturia | 1 | |
| Alopecia | 3 | |
| Pigment change | | |
| Lichen planus | | |
| Other skin reaction | _ | |

Uramustine (91112)

Uracil Mustard

Total reports May 1964-October 1971 2 Reports not listed Nil

| | Total | Deaths |
|---------|-------|--------|
| Anaemia | 1 | |
| Purpura | 1 | |

RadioPhosphorus P-32 (91115)

Total reports October 1967-October 1971 2 (1 fatal) Reports not listed 1

| | | Total | Deaths |
|-----------|-------------------------------|-------|--------|
| Leukaemia | • 3 • • • • • • • • • • • • • | 1 | 1 |

Triethylene thiophosphoramide (91125)

'Thiotepa'

Total reports May 1964-October 1971 15 (11 fatal) Reports not listed Nil

| | Total | Deaths |
|-------------------------------|-------|--------|
| Thrombocytopenia | 1 | |
| Agranulocytosis | 6 | 4 |
| Aplastic anaemia | 6 | 6 |
| Leukaemia | 1 | 1 |
| Abnormal liver function tests | 1 | |

Ethoglucid (91130)

Epodyl

Total reports October 1965-October 1971 2 (1 fatal) Reports not listed Nil

| | Total | Deaths |
|-------------|-------|--------|
| Blindness | 1 | |
| Hypotension | 1 | 1 |

Colchicine (91135)

Colbenemid

Total reports Nay 1964-October 1971 12 (3 fatal) Reports not listed 2 (1 fatal)

| | Total | Deaths |
|--------------------|-------|--------|
| Agranulocytosis | 1 | 1 |
| Haemolytic anaemia | 1 | |
| Leukaemia | 1 | 1 |
| Impotence | 1 | |
| Reduced libido | 2 | |
| Neuritis | 1 | |
| Abdominal pain | 1 | |
| Skin reactions | 2 | |

Demecolcine (91136)

Total reports March 1967-October 1971 1 (1 fatal) Reports not listed Nil

| | Total | Deaths |
|------------------|-------|--------|
| Aplastic anaemia | 1 | 1 |

Vincristine (91138)

Oncovin'

Total reports May 1965-October 1971 19 (3 fatal) Reports not listed Nil

| | Total | Deaths |
|-------------------------------|-------|--------|
| Hypoplastic anaemia | 1 | |
| Neuropathy | 4 | |
| Neuritis | 1 | |
| Paralysis | 1 | |
| Convulsion | 4 | |
| Generalised weakness | 1 | |
| Hypotension (postural) | 1 | 1 |
| Jaundice | 1 | 1 |
| Dysphagia | 1 | |
| Gastro-intestinal haemorrhage | 1 | |
| Ileus | 2 | 1 |
| Diarrhoea | 1 | |

Actinomycin D (91201)

'Sanamycin'

Total reports November 1966-October 1971 1 (1 fatal) Reports not listed Nil

| | | | Total | Deaths |
|--------------|-------------|-------|-------|--------|
| Subarachnoid | haemorrhage | ••••• | 1 | 1 |

Idoxuridine (91301)

'Kerecid'

Total reports September 1969-October 1971 3 (1 fatal) Reports not listed Nil

| | Total | Deaths |
|---------------|-------|--------|
| Jaundice | 1 | 1 |
| Gingivitis | 1 | |
| Skin reaction | 1 | |

DRUGS USED FOR TREATMENT OF PEPTIC ULCER

Carbenoxolone (92150)

'Biogastrone', 'Bioral', 'Duogastrone'

Total reports June 1964-October 1971 122 (3 fatal) Reports not listed 4

| | Total | Deaths |
|-------------------------------|-------|--------|
| Gynaecomastia (male) | 1 | |
| Weightgain | 1 | |
| Oedema | 27 | 1 |
| Fluid retention | 10 | |
| Hypokalaemia | 17 | |
| Hypernatraemia | 1 | · |
| Tetany | 1 | |
| Thrombocytopenia | 1 | |
| Convulsion | 1 | |
| Subarachnoid haemorrhage | 1 | 1 |
| Headache | 7 | |
| Generalised weakness | 1 | |
| Paraesthesia | 1 | |
| Papilloedema | 1 | |
| Visual disturbance | 1 | |
| Hypertension | 11 | |
| Tachycardia | 1 | |
| Heart failure | 8 | |
| Chest pain | 1 | |
| Epistaxis | 1 | |
| Jaundice | 2 | |
| Hepatomegaly not jaundical | 1 | |
| Abnormal liver function tests | 2 | |
| Glossitis | 1 | |
| Diarrhoea | 2 | |
| Abdominal pain | 3 | |
| Urticaria | 1 | |
| Purpura | 2 | |
| Other skin reactions | 3 | |
| Congenital abnormality | 1 | |
| Periarteritis nodosa | 1 | 1 |
| Muscle pain | 5 | |

| Prescriptions | (EC 10) | for | 1968 | 188,000 |
|---------------|---------|-----|------|---------|
| 77 | 11 | п | 1969 | 225,000 |
| п | It | п | 1970 | 190,000 |

LAXATIVES

Phenolphthalein (92341)

'Aragol', 'Alophen', 'Kest', 'Petrolagar', 'Veracolate'

Total reports February 1965-October 1971 15 (4 fatal)
Reports not listed 9 (3 fatal)

| | Total | Deaths |
|----------------|-------|--------|
| Giddiness | 1 | |
| Skin reactions | 5 | 1 |

| Prescriptions | (EC 10) | for | 1968 | 1,139,000 |
|---------------|---------|-----|------|-----------|
| 11 | 11 | 19 | 1969 | 1,092,000 |
| 11 | II . | 11 | 1970 | 984,000 |

LAXATIVES

Bisacody1 (92345)

'Dulcodos', 'Dulcolax'

Total reports August 1964-October 1971 10 Reports not listed 1

| | Total | Deaths |
|-------------------|-------|--------|
| Confusional state | 1 | |
| Conjunctivitis | 1 | |
| Hypotension | 1 | |
| Proctitis | 1 | |
| Constipation | 1 | |
| Skin reactions | 4 | |

| Prescriptions | (EC 10) | for | 1968 | 644,000 |
|---------------|---------|-----|------|---------|
| Ħ | n | п | 1969 | 647,000 |
| II II | 11 | п | 1970 | 642,000 |

Diphenoxylate (92410)

'Lomotil'

Total reports May 1964-October 1971 35 (2 fatal) Reports not listed 4

| | Total | Deaths |
|----------------------|-------|--------|
| Muscle weakness | 1 | |
| Oedema | 1 | |
| Thrombocytopenia | 1 | |
| Haemolytic anaemia | 2 | |
| Depression | 1 | |
| Confusional state | 1 | |
| Somnolence | 1 | |
| Headache | 2 | |
| Sensory disturbance | 1 | |
| Cardiac arrest | 2 | 2 |
| Arrhythmia | 1 | |
| Chest pain | 1 | |
| Jaundice | 2 | |
| Glossitis | 1 | |
| Nausea and vomiting | 3 | |
| Abdominal pain | 1 | |
| Urticaria | 4 | |
| Other skin reactions | 2 | |
| Overdose | 3 | |
| | | |

| Prescriptions | (EC 10) | for | 1968 | 458,000 |
|---------------|---------|-----|------|---------|
| 19 | Ħ | 11 | 1969 | 594,000 |
| n | п | Ħ | 1970 | 591,000 |

Guaiphenesin (99005)

'Ardinex', 'Delexin', Entair', 'Respenyl'

Total reports July 1964-October 1971 31
Reports not listed 16

| | Total | Deaths |
|--------------------------|-------|--------|
| Mental disorder | 1 | |
| Syncope | 1 | |
| Flushing | 1 | |
| Tremor | 1 | |
| Sensory disturbance | 1 | |
| Tachycardia | 1 | |
| Sinusitis | 1 | |
| Diarrhoea | 1 | |
| Nausea and vomiting | 1 | |
| Retention of urine | 1 | |
| Skin reactions | 3 | |
| Congenital abnormalities | 2 | |
| | | |

| Prescriptions | (EC 10) | for | 1968 | 850,000 |
|---------------|---------|-----|------|---------|
| II II | 11 | n | 1969 | 917,000 |
| 11 | n | 11 | 1970 | 765,000 |

Bromhexine Hydrochloride (99100)

'Bisolvon'

Total reports October 1968-October 1971 110 (2 fatal)

Reports not listed 8

| | Total | Deaths |
|---------------------------|-------|--------|
| Pancreatic disorder | 1 | |
| Oedema | 3 | |
| Coagulation defect | 1 | 1 |
| Confusional state | 1 | |
| Syncope | 2 | |
| Somnolence | 2 | |
| Cerebrovascular disorders | 1 | |
| Tremor | 4 | |
| Paraesthesia | 2 | |
| Sensory disturbance | 1 | |
| Palpitations | 2 | |
| Arrhythmia | 1 | |
| Chest pain | 1 | |
| Asthma | 1 | |
| Haemoptysis | 4 | |
| Jaundice | . 3 | |
| Gastric ulcer with | | |
| haemorrhage | 1 | |
| Gastric ulcer with | | |
| perforation | 1 | 1 |
| Colitis | 1 | |
| Gastro-intestinal | | |
| haemorrhage | 2 | |
| Diarrhoea | 11 | |
| Drymouth | 7 | |
| Nausea and vomiting | 16 | |
| Abdominal pain | 8 | |
| Anorexia | 2 | |
| Retention of urine | 3 | |
| Vaginitis | 1 | |
| Urticaria | 4 | |
| Angioneurotic oedema | 2 | |
| Purpura | 1 | |
| Other skin reactions | 12 | |

| Prescriptions | (EC 10) | for | 1968 | 52,000 |
|---------------|---------|-----|------|---------|
| 11 | п | 11 | 1969 | 237,000 |
| II . | 81 | 18 | 1970 | 335,000 |

Disulfiram (99101)

'Antabuse'

Total reports June 1964-October 1971 57 (2 fatal) Reports not listed 2

| | Total | Deaths |
|--------------------|-------|--------|
| Psychosis | 3 | |
| Depression | 1 | |
| Confusional State | 6 | |
| Hallucinations | 1 | |
| Emotional change | 1 | |
| Mental disorder | 1 | • |
| Debility | 1 | |
| Encephalitis | 1 | |
| Neuropathy | 6 | |
| Neuritis | 6 | |
| Convulsion | 1 | |
| Syncope | 2 | 1 |
| Flushing | 1 | |
| Visual disturbance | 1 | |
| Cardiac arrest | 1 | 1 |
| Bronchospasm | 1 | |
| Skin reaction | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 4,000 |
|---------------|---------|-----|------|-------|
| н | Ħ | 19 | 1969 | 7,000 |
| 11 | 19 | Ħ | 1970 | 8,000 |

Dithranol triacetate (99601)

'Exolan'

Total reports September 1966-October 1971 7 Reports not listed 1

| | Total | Deaths |
|----------------|-------|--------|
| Keratitis | 4 | |
| Skin reactions | 2 | |

| Prescriptions | (EC 10) | for | 1968 | 16,000 |
|---------------|---------|-----|------|--------|
| H | Ħ | Ħ | 1969 | 15,000 |
| n | 19 | H | 1970 | 22,000 |

Halquinol (99611)

'Quinolor', 'Quixalin', 'Remiderm', 'Remotic', 'Tarquinor'

Total reports October 1964-October 1971 13

Reports not listed Nil

| | Total | Deaths |
|----------------------|-------|--------|
| Headache | 1 | |
| Nausea and vomiting | 1 | |
| Urticaria | 3 | |
| Other skin reactions | 8 | |
| | | |

| Prescriptions | (EC 10) | for | 1968 | 170,000 |
|---------------|---------|-----|------|---------|
| 11 | 11 | 11 | 1969 | 119,000 |
| 19 | It | ti | 1970 | 212,000 |

Ergometrine (99801)

'Syntometrine'

Total reports August 1964-October 1971 17 (3 fatal)
Reports not listed 1

| | Total | Deaths |
|--------------------------|-------|--------|
| Mania | 1 | |
| Convulsion | 1 | |
| Subarachnoid haemorrhage | 2 | 1 |
| Headache | 1 | |
| Visual disturbance | 3 | |
| Tinnitus | 1 | |
| Hypertension | 3 | |
| Arrhythmia | 1 | |
| Coronary occlusion | 1 | 1 |
| Renal failure | 3 | 1 |
| Skin reaction | 1 | |

| Prescriptions | (EC 10) | for | 1968 | 61,000 |
|---------------|---------|-----|------|--------|
| ı | Ħ | | 1969 | 69,000 |
| 11 | Ħ | Ħ | 1970 | 64,000 |

Sodium Aurothicmalate (99901)

'Myocrisin'

Total reports November 1964-October 1971 41 (19 fatal)
Reports not listed 3 (3 fatal)

| | Total | Deaths |
|-------------------------------|-------|--------|
| Thrombocytopenia | 4 | 1 |
| Leucopenia | 1 | 1 |
| Agranulocytosis | 2 | 2 |
| Pancytopenia | 3 | 2 |
| Aplastic anaemia | 11 | 8 |
| Neuropathy | 1 | |
| Subarachnoid haemorrhage | 2 | 2 |
| Sensory disturbance | 1 | |
| Deep venous thrombosis | 1 | |
| Vasculitis | 1 | |
| Abnormal liver function tests | 1 | |
| Albuminuria | 1 | |
| Purpura | 1 | |
| Exfoliative dermatitis | 2 | |
| Alopecia | 1 | |
| Lichen planus | 1 | |
| Other skin reactions | 2 | |
| Congenital abnormalities | 2 | |
| | | |

| Prescriptions | (EC 10) | for | 1968 | 11,000 |
|---------------|---------|-----|------|--------|
| n | Н | 11 | 1969 | 14,000 |
| H | Ħ | 11 | 1970 | 17,000 |

Dichlorobenzene (99915)

'Cerumol'

Total reports July 1965-October 1971 5
Reports not listed Nil

| | Total | Deaths |
|----------------|-------|--------|
| Otitis externa | 1 | |
| Skin reactions | 4 | |

 Prescriptions
 (EC 10) for 1968
 468,000

 " " " 1969
 415,000

 " " " 1970
 456,000

Cromogycic acid, Disodium salt (99950)

'Intal'

Total reports August 1968-October 1971 72 (7 fatal) Reports not listed 3

| | Total | Deaths |
|-----------------------------|-------|--------|
| Breast hypertrophy (female) | 1 | |
| Diabetes mellitus | 2 | |
| Oedema | 1 | |
| Depression | 2 | |
| Dependence | 1 | |
| Emotional change | ī | |
| Impotence | ī | |
| Syncope | 2 | |
| Somnolence | 1 | |
| Headache | 1 | |
| Migraine | 1 | |
| Tremor | 1 | |
| Sensory disturbance | 1 | |
| Retinitis | 1 | |
| Corneal ulceration | 1 | |
| Labyrinthitis | 1 | |
| Taste abnormality | 1 | |
| Hypertension | 1 | |
| Palpitations | 1 | |
| Cardiac arrest | 3 | 3 |
| Heart failure | 3 | 2 |
| Chest pain | 1 | |
| Bronchospasm | 6 | |
| Dyspnoea | 1 | 1 |
| Rhinitis | 3 | |
| Asthma | 2 | |
| Haemoptysis | 1 | |
| Respiratory symptoms | 1 | |
| Discolouration of teeth | 1 | |
| Stomatitis | 1 | |
| Nausea and vomiting | 4 | |
| Abdominal pain | 3 | |
| Urticaria | 5 | |
| Photosensitivity | 1 | |
| Contact dermatitis | 1 | |
| Moniliasis | 1 | |
| Pruritus | 2 | |
| Other skin reactions | 2 | |
| Anaphylaxis | 1 | |
| Arthralgia | 1 | |
| Muscle pain | 1 | |
| Rebound | 1 | |
| Overdose | 1 | 1 |

| Prescriptions | (EC 10) | for | 1968 | 127,000 |
|---------------|---------|-----|------|---------|
| | 11 | 11 | 1969 | 442,000 |
| 99 | 26 | 19 | 1970 | 847,000 |

D/Vac Pollen vaccine (99965)

Total reports July 1964-October 1971 16 Reports not listed 8

| | Total | Deaths |
|-------------------------------|-------|--------|
| Gastro-intestinal haemorrhage | 1 | |
| Skin reactions | 4 | |
| Anaphylaxis | 1 | |
| Abscess following | | |
| subcutaneous injection | 1 | |
| Abscess following | | |
| Intra-muscular injection | 1 | |

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